Third Edition

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Contact Lens Practice

To Suzanne, Zoe and Bruce

Contact Lens Practice

Third Edition

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PREFACE TO THE THIRD EDITION

This book strives to achieve the 'middle ground' among contact lens textbooks. It is not intended to be a brief clinical manual of contact lens fitting; nor is it intended to be a weighty tome with extensive research coverage. Like its predecessors, this third edition of Contact Lens Practice seeks to be a comprehensive, easily accessible book that provides information of immediate relevance to contact lens practitioners, underpinned by well-founded evidence and expert clinical insight by the authors of the various chapters, each of whom is an expert in the area covered.

This new edition is not just a cosmetic make-over. There have been extensive revisions to most chapters, many of which have been written by authors who are new for this edition. There is also a new chapter on myopia control – an area of considerable interest at present in view of the current myopia epidemic (especially in Asia), and the potential for fitting contact lenses that can arrest myopia progression to a certain degree. The chapter on daily disposable lenses has been updated and expanded, which is particularly important given that this modality now represents nearly one-third of contact lenses prescribed worldwide.

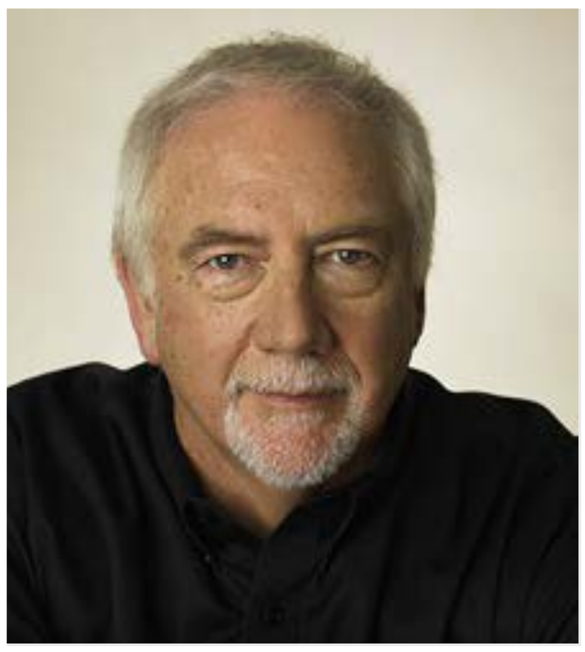
I hope that students using this book find it to be a valuable guide to their studies and acquisition of knowledge in the science and art of contact lens fitting, and I trust that this work will be a valuable companion to practitioners in their efforts to satisfy the needs of those patients fitted with contact lenses.

Professor Nathan Efron AC

TRIBUTES

Here we pay tribute to two contributors to Contact Lens Practice who have passed away since the second edition of this book was published.

Keith Edwards, who wrote the chapter on History Taking in the first two editions of this book, lost a long-fought battle with cancer in 2014. Keith was an inspirational educator, clinician and researcher who had an impact internationally in the field of contact lenses and intraocular lenses. Following his Optometry degree at City University, he worked in private practice and served as secretary of the London Refraction Hospital and examinations advisor at the College of Optometrists. He was an inaugural director of Optometric Educators Ltd and later worked for Madden and Layman, which was acquired by Bausch & Lomb in the late 1980s. He expanded his role from UK Professional Services to Director of Global Clinical Development for Surgical at Bausch & Lomb, which took him to the US, where his final job was as Vice-President of Clinical and Regulatory Affairs at LENSAR.



Brien Holden, who co-authored the chapter in this book on Myopia Control, passed away suddenly in 2015. He was Chief Executive Officer of the Brien Holden Vision Institute and Professor at the School of Optometry and Vision Science at the University of New South Wales, Australia. Professor Holden was a global leader in eye care and vision research, and an internationally renowned and awarded scientist and humanitarian. He was widely acknowledged as the most influential optometrist of our generation. His career was spent inspiring scientists and health-care professionals around the world with his dream of 'vision for everyone, everywhere'. Professor Holden was the recipient of seven honorary doctorates from universities around the world, and was awarded an Order of Australia Medal for his work in eye health and vision science.

ACKNOWLEDGEMENTS

I am grateful to the contributing authors of this third edition of Contact Lens Practice. All have worked diligently to update their chapters, or write new chapters, to bring the latest clinically relevant information to the fore.

I continue to enjoy the strong support of the long-standing publisher of all of my books – Elsevier. In particular, I am grateful to Russell Gabbedy (Commissioning Editor) and Alexandra Mortimer (Development Editor) for their encouragement and support during the planning and production of this book. Thanks also to Samuel Crowe, for assisting efficiently with various aspects of production.

Editing a book of this size and scope is a substantial undertaking, and in this regard I wish to offer special thanks to my lovely wife, Suzanne, who has served as a 'virtual co-editor' by way of spending many long hours assisting me in assembling, editing, organizing and proof reading the contributed material. She has done a wonderful job. I really could not have completed this task without her assistance. I also thank Suzanne for co-authoring Chapters 22 and 29 with me, and for revising and authoring Chapter 30.

Let me also pay tribute to the photographers and illustrators, many of whom were not contributing authors of this book, for their extraordinary skills and insights in creating such fantastic imagery. I also thank them for giving me permission to use this material in the book. I apologize if I have made any errors in attribution; please let me know if I have erred in this regard, and I shall correct this at the first reprinting opportunity.

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Introduction

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1

History

NATHAN EFRON

Introduction

> We cannot continue these brilliant successes in the future, unless we continue to learn from the past.
>
> Calvin Coolidge, inaugural US presidential address, 1923

Coolidge was referring to the successes of a nation, but his sentiment could apply to any field of endeavour, including contact lens practice. As we continue to ride on the crest of a huge wave of exciting developments in the 21st century, we would not wish to lose sight of the past. Hence the inclusion in this book of this brief historical overview.

Outlined below in chronological order (allowing for some historical overlaps) is the development of contact lenses, from the earliest theories to present-day technology. Each heading, which represents a major achievement, is annotated with a year that is considered to be especially significant to that development. These dates are based on various sources of information, such as dates of patents, published papers and anecdotal reports. It is recognized, therefore, that some of the dates cited are open to debate, but they are nevertheless presented to provide a reasonable chronological perspective.

Early Theories (1508–1887)

Although contact lenses were not fitted until the late 19th century, a number of scholars had earlier given thought to the possibility of applying an optical device directly to the eyeball to correct vision. Virtually all of these suggestions were impractical.

Many contact lens historians point to Leonardo da Vinci's Codex *of* the Eye, Manual D, written in 1508, as having introduced the optical principle underlying the contact lens. Indeed, da Vinci described a method of directly altering corneal power – by immersing the eye in a bowl of water (Fig. 1.1). Of course, a contact lens corrects vision by altering corneal power. However, da Vinci was primarily interested in learning the mechanisms of accommodation of the eye (Heitz and Enoch, 1987) and did not refer to a mechanism or device for correcting vision.

In 1636, René Descartes described a glass fluid-filled tube that was to be placed in direct contact with the cornea (Fig. 1.2). The end of the tube was made of clear glass, the shape of which would determine the optical correction. Of course, such a device is impractical as blinking is not possible; nevertheless, the principle of directly neutralizing corneal power used by Descartes is consistent with the principles underlying modern contact lens design (Enoch, 1956).

As part of a series of experiments concerning the mechanisms of accommodation, Thomas Young, in 1801, constructed a device that was essentially a fluid-filled eyecup that fitted snugly into the orbital rim (Young, 1801) (Figs. 1.3 and 1.4). A microscope eyepiece was fitted into the base of the eyecup, thus forming a similar system to that used by Descartes. Young's invention was somewhat more practical in that it could be held in place with a headband and blinking was possible; however, he did not intend this device to be used for the correction of refractive errors.

In a footnote in his treatise on light in the 1845 edition of the Encyclopedia Metropolitana, Sir John Herschel suggested two possible methods of correcting 'very bad cases of irregular cornea': (1) 'applying to the cornea a spherical capsule of glass

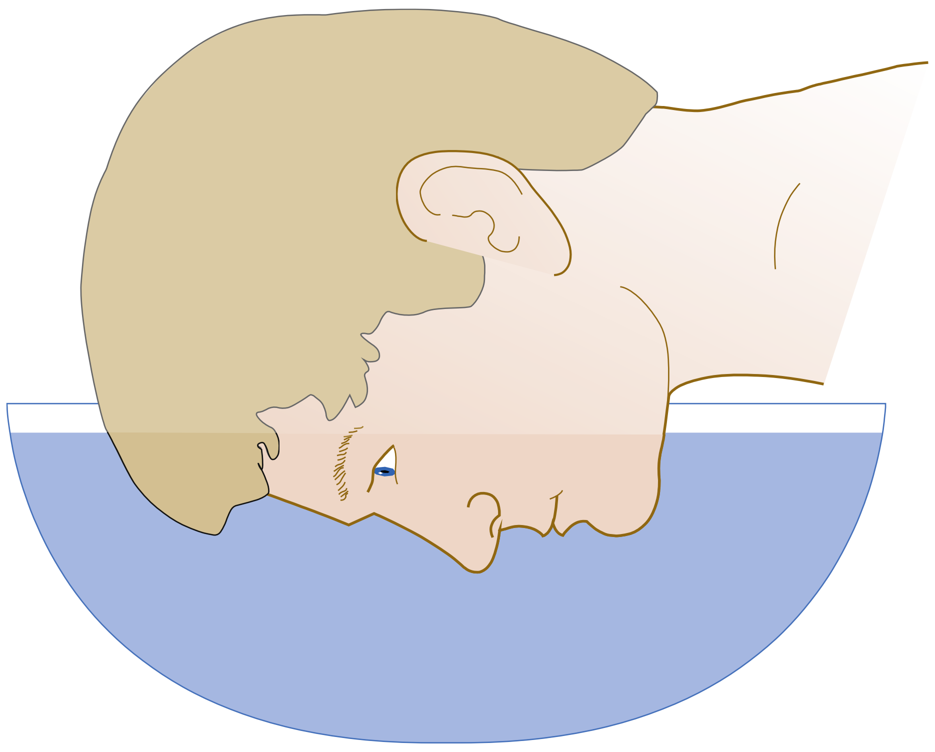

Fig. 1.1 Idea of Leonardo da Vinci to alter corneal power.

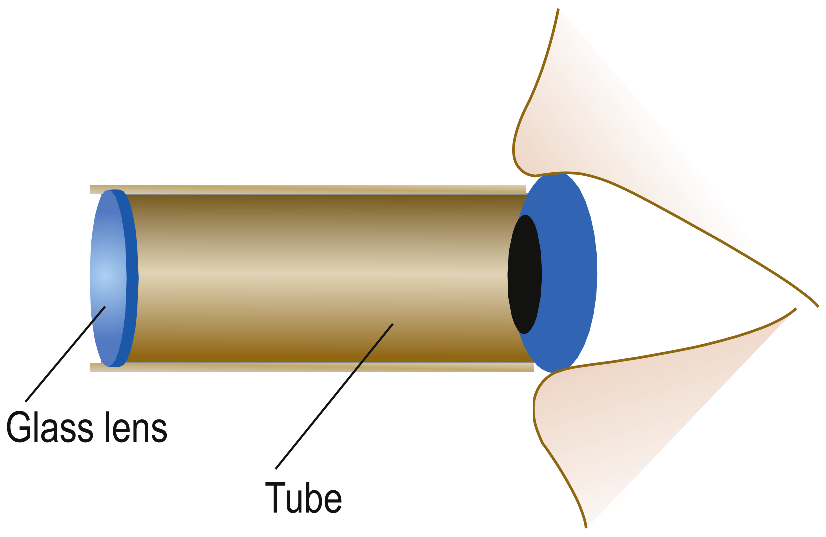

Fig. 1.2 Fluid-filled tube described by René Descartes.

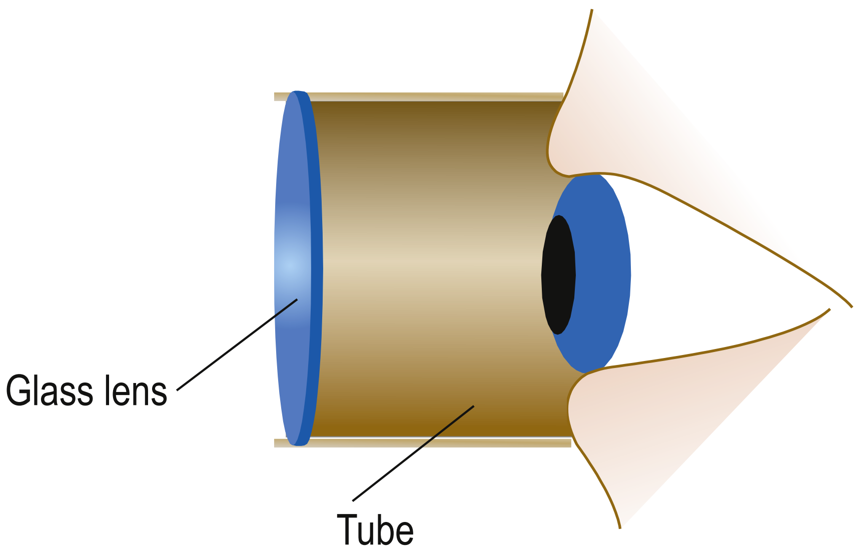

Fig. 1.3 Eyecup design of Thomas Young.

Fig. 1.4 Thomas Young.

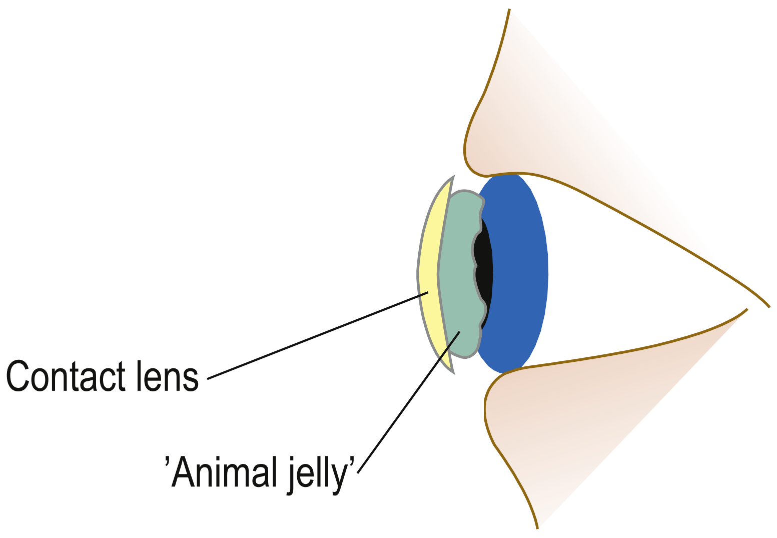

Fig. 1.5 'Animal jelly' sandwiched between a 'spherical capsule of glass' (contact lens) and cornea, as proposed by Sir John Herschel.

filled with animal jelly' (Fig. 1.5), or (2) 'taking a mould of the cornea and impressing it on some transparent medium' (Herschel, 1845). Although it seems that Herschel did not attempt to conduct such trials, his latter suggestion was ultimately adopted some 40 years later by a number of inventors, working independently and unbeknown to each other, who were all apparently unaware of the writings of Herschel.

Glass Scleral Lenses (1888)

There was a great deal of activity in contact lens research in the late 1880s, which has led to debate as to who should be given credit for being the first to fit a contact lens. Adolf Gaston Eugene Fick (Fig. 1.6), a German ophthalmologist working in Zurich, appears to have been the first to describe the process of fabricating and fitting contact lenses in 1888; specifically, he described the fitting of afocal scleral contact shells first on rabbits, then on himself and finally on a small group of volunteer patients (Efron and Pearson, 1988). In their textbook dated 1910, Müller and Müller, who were manufacturers of ocular prostheses, described the fitting in 1887 of a partially transparent protective glass shell to a patient referred to them by Dr Edwin Theodor Sämisch (Müller and Müller, 1910). Pearson (2009) asserts that the fitting was done by Albert C Müller-Uri. Fick's work was published in the journal Archiv *für* Augenheilkunde in March 1888, and must be accorded historical precedence over later anecdotal textbook accounts.

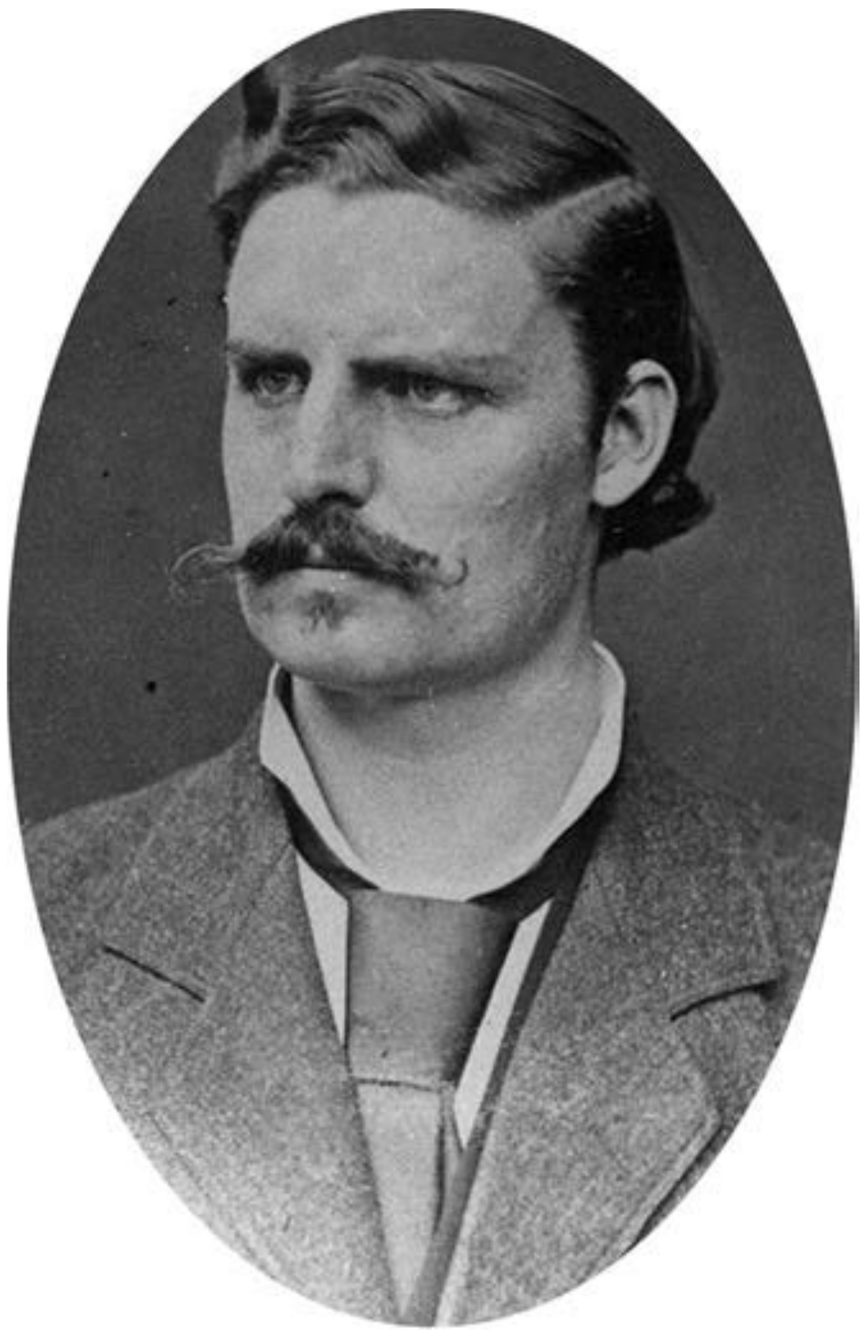

Fig. 1.6 Adolf Gaston Eugene Fick.

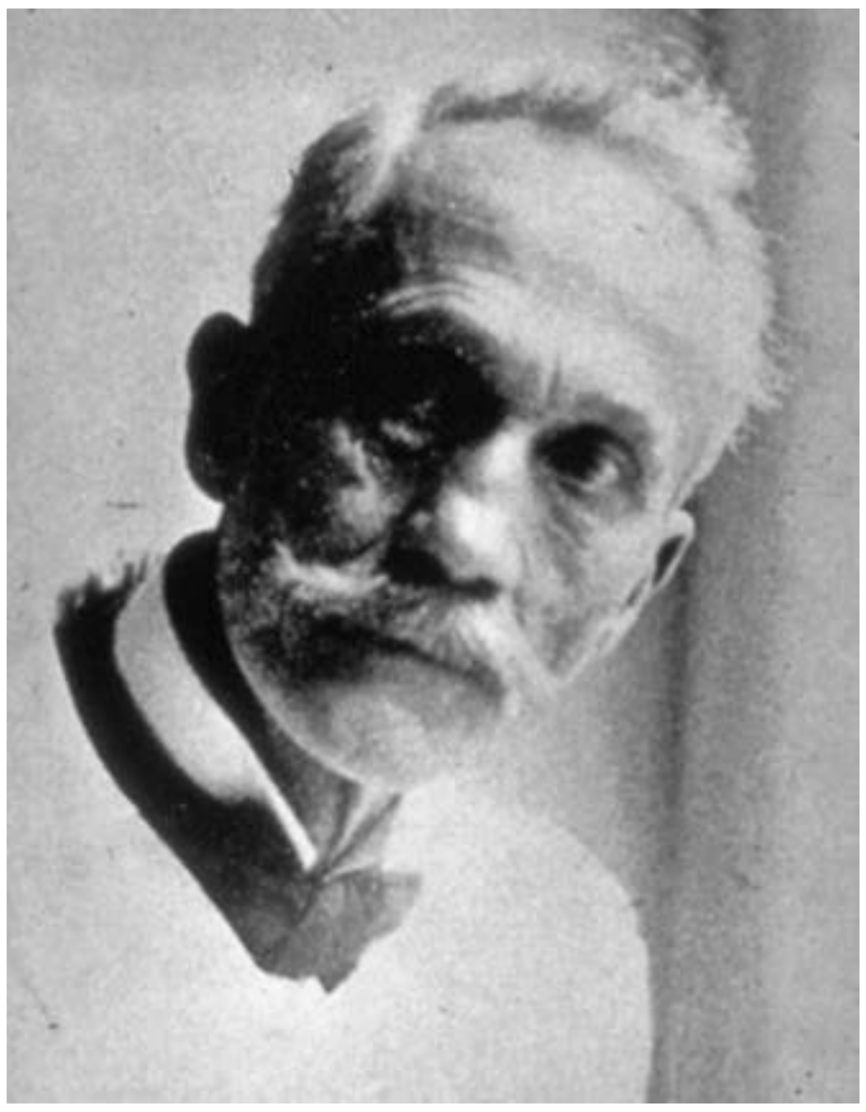

Fig. 1.7 Eugène Kalt.

French ophthalmologist Eugène Kalt (Fig. 1.7) fitted two keratoconic patients with afocal glass scleral shells and obtained a significant improvement in vision. A report of this work, presented to the Paris Academy of Medicine on 20 March, 1888 by Kalt's senior medical colleague, Professor Photinos Panas, acknowledges and therefore effectively confirms that the work of Fick occurred earlier (Pearson, 1989).

Credit for fitting the first powered contact lens must be given to August Müller (Fig. 1.8) (no relation to Müller and Müller, mentioned above), who conducted his work while he was a medical student at Kiel University in Germany (Pearson and Efron, 1989). In his inaugural dissertation presented to the Faculty of Medicine in 1889, Müller described the correction of his own high myopia with a powered scleral contact lens. Paradoxically, Müller subsequently lost interest in ophthalmology and went on to practise as an orthopaedic specialist.

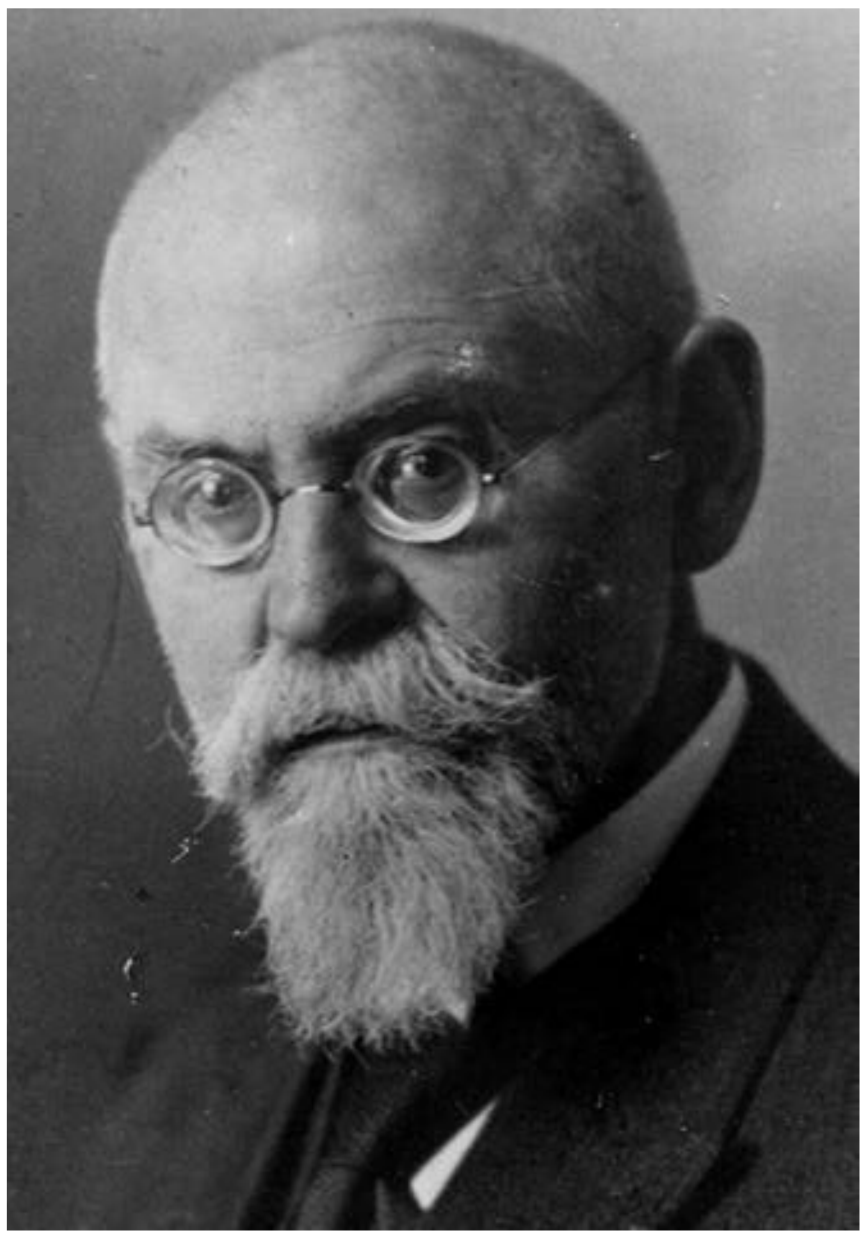

Fig. 1.8 August Müller. (Courtesy of Richard Pearson.)

The lenses worn by Müller were made by an optical engineer, Karl Otto Himmler (1841–1903), whose firm enjoyed, until the outbreak of World War II, an international reputation for the manufacture of microscopes and their accessories. Himmler must therefore be acknowledged as the first manufacturer of optically ground contact lenses (Pearson, 2007).

Little development occurred in the 50 years subsequent to these early clinical trials. Improvements in methods of scleral lens fitting were described by clinicians such as Dallos, who emphasized the importance of designing the lens to facilitate tear flow beneath the lens (Dallos, 1936). Dallos also went on to develop techniques for taking impressions of the human eye and grinding the lenses from these impressions.

Plastic Scleral Lenses (1936)

Carl Zeiss of Jena, Germany applied for a patent that proposed the manufacture of contact lenses from 'cellon, celluloid or an organic substance with similar mechanical and optical properties', which was eventually issued in 1923 (Pearson, 2015). Cellon is cellulose acetate and celluloid is cellulose nitrate plasticized with camphor; therefore, this is a reference to a lens made of a plastic material. This was also the first mention of the manufacture of contact lenses by moulding. The Zeiss patents envisaged that contact lenses made from plastic materials would be less expensive, have some flexibility that would improve the fit, be 'unbreakable' and offer ocular protection (Pearson, 2015).

It appears that in Germany there may have been some largely unsuccessful attempts to fit plastic lenses from around 1930. It was reported in that year that Zeiss contact lenses moulded from cellon and celluloid lacked the degree of polish achieved with glass lenses and were unstable owing to the influences of humidity and temperature. More serious findings were that they put a 'tourniquet' on the conjunctiva in the region of the limbus and caused extensive corneal erosion. These unfavourable results were possibly due to the fact that they were made with a single back scleral radius of 12 mm (Pearson, 2015).

The Rohm and Haas company introduced transparent plastic (polymethyl methacrylate: PMMA) into the USA in 1936, and in the same year Feinbloom (1936) described a scleral lens consisting of an opaque plastic haptic portion and a clear glass centre. Soon after, scleral lenses were fabricated entirely from PMMA using lathing techniques. The earliest report of the fitting of PMMA lenses appears to have been made by Thier in 1939. These lenses were said to be 'about half the weight of ordinary glass, unbreakable and quicker to manufacture'. They did not provoke any irritation, but the optical zone needed to be repolished every 6 months (Pearson, 2015).

A key rationale for using PMMA for the manufacture of contact lenses was that this material was considered to be biologically inert in the eye. This view was formed by military medical officers who examined the eyes of pilots who suffered eye injuries during World War II as a result of fragments from shattered cockpit windscreens (as would occur during aerial dogfights) becoming permanently embedded in the eye. These eyes remained unreactive for years after such accidents. Other advantages of PMMA included its light weight, break resistance and being easy to lathe and polish.

Plastic Corneal Lenses (1948)

The development of corneal lenses – or rigid lenses, as they are referred to today – began as the result of an error in the laboratory of optical technician Kevin Tuohy. During the lathing of a PMMA scleral lens, its haptic and corneal portions separated. Tuohy became curious as to whether the corneal portion could be worn, so he polished the edge, placed it in his own eye and found that the lens could be tolerated (Braff, 1983). Further trials were conducted, leading to the development of the rigid contact lens (rigid lenses were previously referred to as 'hard' lenses if they were manufactured from PMMA). Tuohy filed a patent for his invention in February 1948.

So began an era of popularization of the contact lens. The spherical Tuohy lens design suffered from two main drawbacks: considerable apical bearing, which caused central corneal abrasion and oedema, and excessive edge lift, which made the lens easy to dislodge. It was soon realized that these problems could be overcome by altering the peripheral curvature of the posterior lens surface, heralding the development of multicurve and aspheric designs, which remain in widespread use today, albeit with superior gas-permeable materials (PMMA is now virtually obsolete).

Silicone Elastomer Lenses (1965)

Silicone rubber forms a unique category amongst contact lens materials. It is a 'soft lens' in terms of its physical behaviour and lenses are fabricated from this material in the form of a soft lens. Unlike all other soft lens materials, silicone elastomer does not contain water and in this respect is analogous to a hard lens material. Silicone elastomer is highly permeable to oxygen and carbon dioxide and therefore provides minimal interference to corneal respiration; however, it is difficult to manufacture and its surface is hydrophobic and must be treated to allow comfortable wear. The considerable difficulties involved in enhancing surface wettability have limited the clinical application of this lens, and few advances have been made since it was originally fitted. The precise date of silicone elastomer lenses becoming commercially available is unclear. There was some patent activity in the mid 1960s to early 1970s, and Mandell (1988) claims to have personally observed ten patients who were wearing such lenses in 1965, noting very poor clinical results.

Soft Lenses (1972)

Possibly the greatest understatement that can be found in the literature pertaining to contact lens development is the final sentence of a paper entitled 'Hydrophilic gels for biological use', published in Nature on 9 January, 1960, by Wichterle and Lim (1960): 'Promising results have also been obtained in experiments in other cases, for example, in manufacturing contact lenses, arteries, etc.'

Initial attempts by Otto Wichterle (Fig. 1.9) to produce soft lenses fabricated from hydroxyethyl methacrylate (HEMA), and manufactured using cast moulding, met with limited success. Unable to attract support from the Institute of Macromolecular Research in Czechoslovakia (now the Czech Republic) where he worked, and indeed discouraged by his superiors, Wichterle was forced to conduct further secret experiments in his own home. Working with a children's mechanical construction kit, Wichterle developed the spin-casting technique (Fig. 1.10) and eventually managed to persuade his peers to conduct further trials at the Institute. He claims to have produced 'the first suitable contact lenses' in late 1961 (Wichterle, 1978), which presumably approximates to the first occasion when a soft lens was actually worn on a human eye. The patent to develop soft contact lenses commercially was subsequently acquired by Bausch & Lomb in the USA, who introduced soft lenses into the world market in 1972.

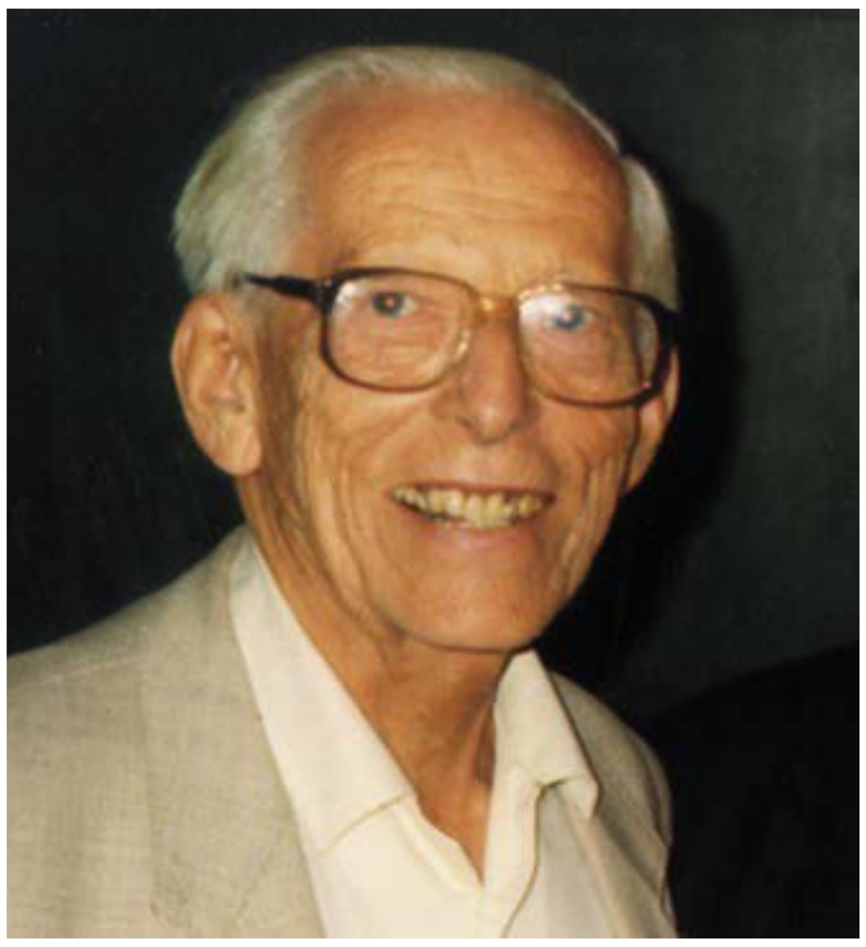
Fig. 1.9 Otto Wichterle. (Courtesy of Debbie Sweeney.)

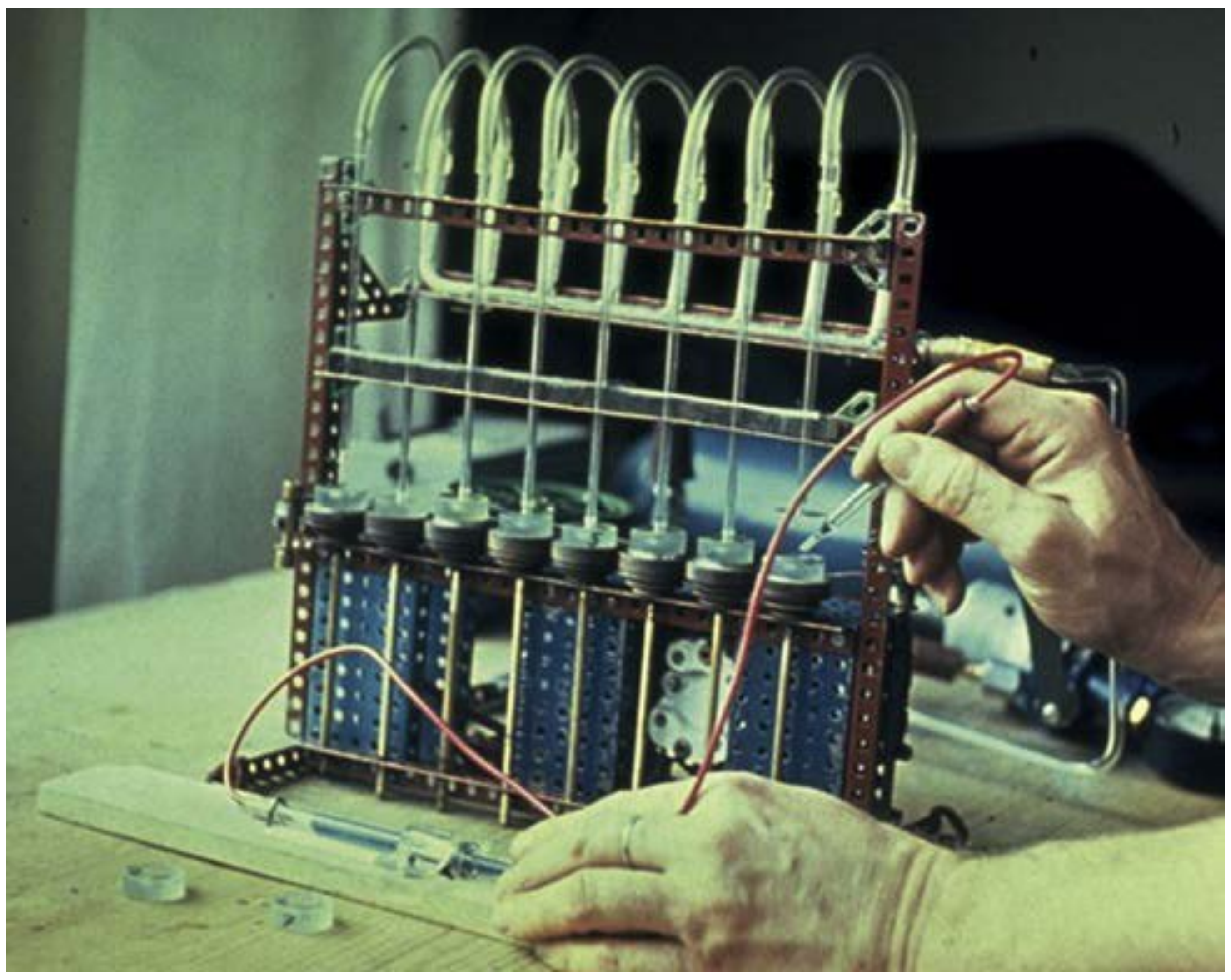
Fig. 1.10 The prototype spin-casting machine built at home by Wichterle using his son's toy Meccano construction set.

Lenses manufactured from HEMA were an immediate market success, primarily by virtue of their superior comfort and enhanced biocompatibility. However, clinical experience and laboratory studies indicated that the poor physiological response of the anterior eye during wear of the early thick HEMA lenses could be enhanced by making soft lenses more permeable to oxygen – specifically by making them thinner and of a higher water content. Much of the research and development in contact lenses up to the present time has been concerned with the development of materials and lens designs that optimize biocompatibility, primarily by enhancing corneal oxygenation and minimizing absorption of proteins, lipids and other tear constituents (McMahon and Zadnik, 2000).

Rigid Gas-permeable Lenses (1974)

In most respects, PMMA is considered to be an ideal contact lens material; however, its single drawback is its impermeability to gases that are exchanged at the corneal surface as part of aerobic metabolism. Specifically, oxygen is prevented from moving from the atmosphere into the cornea, and carbon dioxide efflux into the atmosphere is impeded. This drawback has been the major driving force in the development of rigid lens materials that are permeable to gases.

One of the first rigid gas-permeable materials to be tried was cellulose acetate butyrate, which afforded some oxygen permeability but was subject to warpage. In 1974, Norman Gaylord managed to incorporate silicone into the basic PMMA structure, heralding the introduction of a new family of contact lens polymers known as silicone acrylates (Gaylord, 1974). Subsequently, other ingredients such as styrene and fluorine have been incorporated into rigid materials in attempts to enhance material biocompatibility further.

Disposable Lenses (1988)

In the early days of soft lens development, patients would typically use the same pair of lenses until the lenses became too uncomfortable to wear, caused severe eye reactions, or were damaged or lost. It became apparent that lens deposition and spoilation over time were major impediments to successful long-term lens wear. Although regular lens replacement was an obvious solution to some of these problems, the high unit cost of lenses proved to be a significant disincentive. In the early 1980s, forward-thinking practitioners – notably Klas Nilsson of Gothenburg, Sweden – convinced patients of the benefits of replacing lenses on a regular basis (6-monthly in Nilsson's case) and began prescribing lenses in this way. A subsequent landmark scientific publication co-authored by Nilsson – known as the 'Gothenburg study' (Holden et al., 1985) – unequivocally proved the benefits of regular lens replacement. So was born the concept of regular lens replacement, albeit relatively expensive for the patient at the time.

If regular lens replacement were to become the norm, something had to be done about lens cost. A group of Danish clinicians and engineers, led by ophthalmologist Michael Bay, developed a moulding process so that low-cost, multiple individual lens packs could be produced (Mertz, 1997). This product – known as 'Danalens' – was released into the Scandinavian market in 1984 and must be recognized as the first truly disposable lens. However, the initial manufacturing process was crude and numerous problems with the lenses and packaging were reported (Benjamin et al., 1985; Bergmanson et al., 1987).

The pharmaceutical giant Johnson & Johnson, which had not previously been involved in the contact lens business, purchased the Danalens technology in 1984 and completely overhauled the lens polymer formulation, packaging system and moulding technology (Mertz, 1997). The result was the Acuvue lens, an inexpensive weekly-replacement extended-wear lens, which was released in the USA in June 1988, and worldwide shortly thereafter. The success of this lens elevated Johnson & Johnson to a leadership position in the contact lens market. All other major contact lens companies followed suit, and today the majority of soft lenses prescribed worldwide (85%) are designed to be replaced monthly or more frequently (Morgan et al., 2015).

Daily Disposable Lenses (1994)

The ultimate frequency with which lenses can be replaced is daily. A Scottish company, Award (which was acquired by Bausch & Lomb in 1996), developed a manufacturing technique whereby the male half of the mould that formed the lens became the lens packaging. This technique further reduced the unit cost of a lens, making daily disposability a viable proposition. The 'Premier' daily disposable lens was launched in the UK in 1994. Johnson & Johnson released the '1-Day Acuvue' daily disposable lens into western regions of the USA around the same time, leading to an ongoing dispute as to which company (Award or Johnson & Johnson) was the first to release a daily disposable contact lens into the market (Meyler and Ruston, 2006). CIBA Vision entered the daily disposable lens market in 1997 with a product called 'Dailies'.

Silicone Hydrogel Lenses (1998)

The allure of a soft contact lens made from a material with a phenomenally high oxygen performance never escaped the contact lens industry. The development of such a lens would be critical to solving hypoxic lens-related problems, which severely limit the clinical utility of contact lenses, especially for extended wear. Silicone elastomers were the obvious answer, but, for reasons outlined above, successful lenses could never be produced from this material. Polymer scientists in the contact lens industry had long recognized that many of the problems associated with silicone elastomers for contact lens fabrication could theoretically be overcome by creating a silicone–hydrogel hybrid.

After more than a decade of intensive research and development, two spherical-design silicone hydrogel lenses were introduced into the market in 1998: Focus Night & Day (CIBA Vision) and Purevision (Bausch & Lomb). The introduction of these lenses is considered by many to be the most significant advance in contact lens material technology since the development of HEMA by Wichterle in the 1960s. Within a decade of these products entering the market, all major contact lens manufacturers had introduced silicone hydrogel lenses; this lens type is now available in toric and multifocal designs and a range of replacement modalities, including daily disposable lenses.

Myopia Control Lenses (2010)

In 2010, CooperVision released into some Asian markets a daily disposable soft lens that is designed to arrest the rate of progression of myopia. A variety of optical designs can be employed to achieve this so-called 'anti-myopia' effect. The CooperVision MiSight lens has a 'dual-focus' design that contains a large central correction area surrounded by concentric zones of alternating distant and near powers. The near power is intended as a 'treatment' zone to prevent myopic progression (see Chapter 33 for a detailed account of myopia control lenses).

Contact Lens 'Flat Pack' (2011)

Japanese manufacturer Menicon introduced an ultra-thin form of packaging – known as the 'flat pack' – for their 'Magic' brand of daily disposable contact lenses. As well as being highly efficient for storage and convenient for the user, this form of packaging reduces lens contamination because the lens back surface is always presented to the patient upon opening the pack, which means that the person can pick up and insert the lens into the eye without touching and contaminating the posterior lens surface, which comes into contact with the eye (Nomachi et al., 2013). The contact lens is essentially sandwiched within a 1 mm thick aluminium foil sleeve that is resistant to evaporation, thus preserving the small amount of fluid trapped within the pack that moisturizes the lens.

Fig. 1.11 presents a historical timeline of key developments in the contact lens field from the time contact (scleral) lenses were first fitted to human eyes in the late 1880s up to the present.

The Future

Soft lenses are likely to dominate the future contact lens market. Although rigid lenses are seldom fitted today for purely cosmetic reasons, there are many clinical indications for rigid lenses, such as keratoconus, distorted corneas, irregular and / or high astigmatism, certain anterior eye pathologies and participation in extreme sports. Accordingly, specialized rigid lens fittings will continue to be an important aspect of contact lens practice, albeit at relatively low levels. The recent renewed interest in scleral or mini-scleral lenses is unlikely to have a significant impact on the overall proportion of lenses prescribed owing to the specialist nature of fitting such lenses.

The convenience and ocular health benefits of daily disposable lenses are likely to see this modality of lens wear continue to increase in popularity. This trend will be accelerated with improvements in methods and efficiency of lens mass production, which in turn will drive prices down and make these lenses more affordable. Of course, any increase in daily disposable lens usage will be matched by a commensurate decrease in the demand for, and use of, contact lens care solutions.

Silicone hydrogels are set to continue as the main material type from which lenses are fabricated in view of their ability to obviate hypoxic complications of lens wear; however, the possibility of the arrival in the future of an entirely new

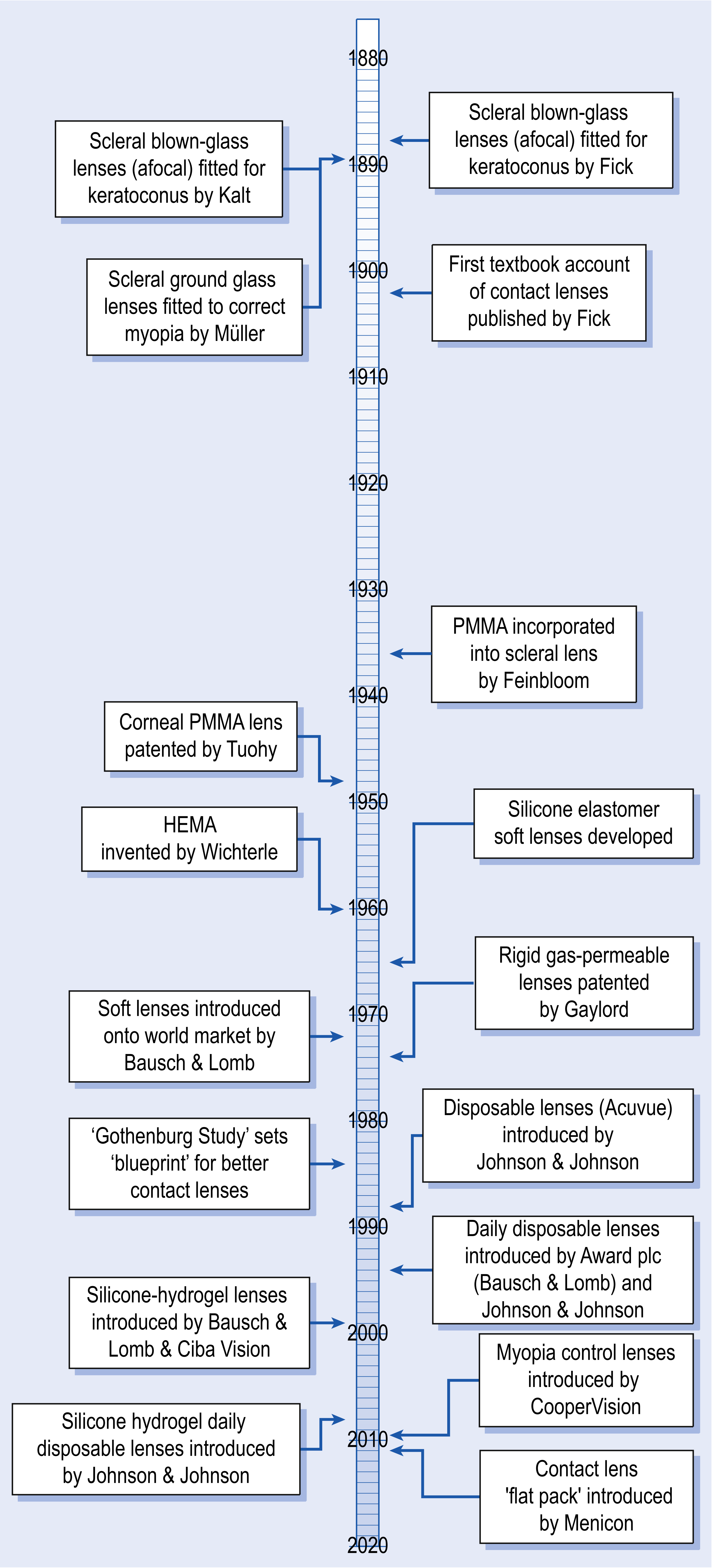
1880
Scleral blown-glass lenses (afocal) fitted for keratoconus by Fick
Scleral blown-glass lenses (afocal) fitted for keratoconus by Kalt
1890
Scleral ground glass lenses fitted to correct myopia by Müller
1900
First textbook account of contact lenses published by Fick
1910
1920
1930
PMMA incorporated into scleral lens by Feinbloom
1940
Corneal PMMA lens patented by Tuohy
1950
Silicone elastomer soft lenses developed
HEMA invented by Wichterle
1960
Rigid gas-permeable lenses patented by Gaylord
Soft lenses introduced onto world market by Bausch & Lomb
1970
Disposable lenses (Acuvue) introduced by Johnson & Johnson
1980
'Gothenburg Study' sets 'blueprint' for better contact lenses
1990
Daily disposable lenses introduced by Award plc (Bausch & Lomb) and Johnson & Johnson
Silicone-hydrogel lenses introduced by Bausch & Lomb & Ciba Vision
2000
Myopia control lenses introduced by CooperVision
Silicone hydrogel daily disposable lenses introduced by Johnson & Johnson
2010
Contact lens 'flat pack' introduced by Menicon
2020

Fig. 1.11 Historical timeline of contact lens development. PMMA = polymethyl methacrylate; HEMA = hydroxyethyl methacrylate.

category of lens material with even greater benefits should not be discounted.

Contact lenses are likely to be used increasingly for the correction of presbyopia; this trend may be fuelled by the development of superior multifocal lens designs and the increasing availability of such products as daily disposable lenses. Looking further into the future, contact lenses that switch power electronically or through some other means may facilitate enhanced presbyopic correction.

Extended wear is the ultimate modality in terms of patient convenience, but it is unlikely that this modality of lens wear will break through the 'glass ceiling' of a prescribing rate of around 10% of lenses fitted in the foreseeable future, in view of the five times greater risk of microbial keratitis when sleeping in all forms of contact lenses (Schein et al., 1989). Again, development or invention of an entirely new category of lens material with superior ocular biocompatibility or an ability to minimize microbial colonization would need to be developed before extended wear can capture an appreciably greater slice of the contact lens market.

As better toric lens designs become available, especially in daily disposable modality, toric lenses fitting is likely to increase steadily to represent approximately 45% of all soft lenses prescribed, which is the level at which all astigmatism ≥ 0.75 D is being corrected. We may see a resurgence in tinted lens fitting as the newly developed coloured silicone hydrogel lenses gain in popularity and similar products enter the market.

Finally, current developments in innovative contact lens applications – such as lens surface modifications to include channels and patterns for improving post-lens tear exchange (Weidemann and Lakkis, 2005; Lin et al., 2006), alternative anti-myopia designs (Sankaridurg et al., 2011), anti-infective and anti-inflammatory lenses (Weisbarth et al., 2007; Zhu et al., 2008), drug delivery (Mohammadi et al., 2014), glucose monitoring and other forms of metabolic sensing (Farandos et al., 2015), intraocular pressure measurement (Chen et al., 2014), digital information acquisition and display (e.g. a contact lens version of Google Glass [Google Inc., Mountain View, CA]) and liquid crystal diode optical switching (Milton et al., 2014) – may open up whole new markets for contact lenses and move at least part of the industry in new and interesting directions. Contact lens practitioners may need to acquire new knowledge and fitting skills so that they can embrace any such innovative developments.

Access the complete references list online at http://www.expertconsult.com.

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2

Anterior Eye

JOHN G LAWRENSON

Introduction

A critical aspect of contact lens practice is monitoring the ocular response to lens wear, which ranges from acceptable physiological changes to adverse pathology. In order to do this, practitioners must possess a thorough understanding of the normal structure and function of the anterior eye, which is the subject of this chapter. In the course of reading other chapters in this book, the reader may need to refer back to this chapter on the functional anatomy and physiology of the anterior eye in order to develop a fuller understanding of the phenomena being described.

The Cornea

The cornea fulfils two important functions: together with the sclera it forms a tough fibrous outer coat that encloses the ocular tissues and protects the internal components of the eye from injury. Significantly, the cornea also provides two-thirds of the refractive power of the eye. It is particularly well suited to its role: the cornea is curved and transparent, and the air–tear interface provides a refractive surface of good optical quality.

CORNEAL ANATOMY

Gross Anatomy

The cornea is elliptical when viewed from in front, with its long axis in the horizontal meridian (Table 2.1). This asymmetry is produced by a greater degree of overlap of the peripheral cornea by opaque limbal tissue in the vertical meridian. The surface area of the cornea is 1.1 cm^2, which represents about 7% of the surface area of the globe (Maurice, 1984). Topographically, the cornea is conventionally divided into four zones (central, paracentral, peripheral and limbal). The central zone, which covers the entrance pupil of the eye, is spherical, approximately 4 mm wide, and principally determines high-resolution image formation on the fovea. The paracentral zone, which lies outside the central zone, is flatter and becomes optically important in dim illumination when the pupil dilates. The peripheral zone is where the cornea is flattest and most aspheric (Klyce et al., 1998). Due to a difference in curvature between its posterior and anterior surfaces, the cornea shows a regional variation in thickness. Centrally the thickness is approximately 0.54 mm (Doughty and Zaman, 2000), with a peripheral thickness between 11% and 19% higher than in the centre (Khoramnia et al., 2007).

TABLE 2.1 Corneal Dimensions and Related Measurements

Parameter	Value
Area	1.1 cm^2
Diameter	
Horizontal	11.8 mm
Vertical	10.6 mm
Radius of curvature	
Anterior central	7.8 mm
Posterior central	6.5 mm
Thickness	
Central	0.54 mm
Peripheral	0.67 mm
Refractive index	1.376
Power	42 D

(Data adapted from Bron et al., 1997.)

Microscopic Anatomy

When the cornea is viewed in transverse section, five distinct layers can be resolved: epithelium, Bowman's layer, stroma, Descemet's membrane and endothelium (Fig. 2.1).

Epithelium. The epithelium represents approximately 10% of the thickness of the cornea (55 µm) (Feng and Simpson, 2008). It is a stratified squamous non-keratinized epithelium, consisting of 5–6 layers of cells (Fig. 2.2), which undergo a constant process of cyclic

Fig. 2.1 Transverse section through the cornea. The stroma, which represents 90% of the thickness of the cornea, is bounded by the epithelium (asterisk) and endothelium (arrow).

shedding and replacement to maintain corneal integrity. Three distinct epithelial cell types are recognized: a single row of basal cells, 2–3 rows of wing cells and 2–3 layers of superficial (squamous) cells. In addition, several non-epithelial cells are present (e.g. lymphocytes, macrophages and Langerhans cells). The epithelium forms a permeability barrier to water, ions and hydrophilic molecules above a certain size, as well as forming an effective barrier to the entry of pathogens. Further epithelial specialization enhances adhesion between cells, to withstand shearing and abrasive forces. Furthermore, throughout the thickness of the epithelium, adjacent cells are connected to one another by water channels (aquaporins) that are engaged in transcellular water transport and gap junctions to allow the transfer of ions and small molecules between cells (Bron et al., 2015).

Superficial cells are structurally modified for their barrier function and interaction with the tear film. Scanning electron microscopy of surface cells shows extensive finger-like and ridge-like projections (microvilli and microplicae), which increase the epithelial surface area. Light, medium and dark cells can be distinguished depending on the number and pattern of surface projections (Pfister, 1973). It has been suggested that dark cells, which are relatively free of these surface features, are close to being desquamated into the tear film. By contrast, the newly arrived light cells possess a more extensive array of surface projections. In high-power transmission electron micrographs, microvilli and microplicae show an extensive filamentous covering known as the glycocalyx. The glycocalyx is formed from membrane-bound mucin glycoproteins and is important for spreading and attachment of the precorneal tear film. In accordance with their barrier function, a complex network of tight junctions links superficial cells that exclude water-soluble dyes such as fluorescein (Bron et al., 2015).

Wing cells are so named because of their characteristic shape, with lateral extensions and a concave inferior surface to accommodate the apices of the basal cells. Their nuclei tend to be spherical or elongated in the plane of the cornea. The cell borders of the polygonal wing cells show prominent infoldings that interdigitate with adjacent cells, and numerous desmosomes. This arrangement results in a strong intercellular adhesion. The cytoplasm contains prominent cytoskeletal elements (predominantly actin and cytokeratin intermediate filaments), and although the usual complement of organelles is present they are few in number.

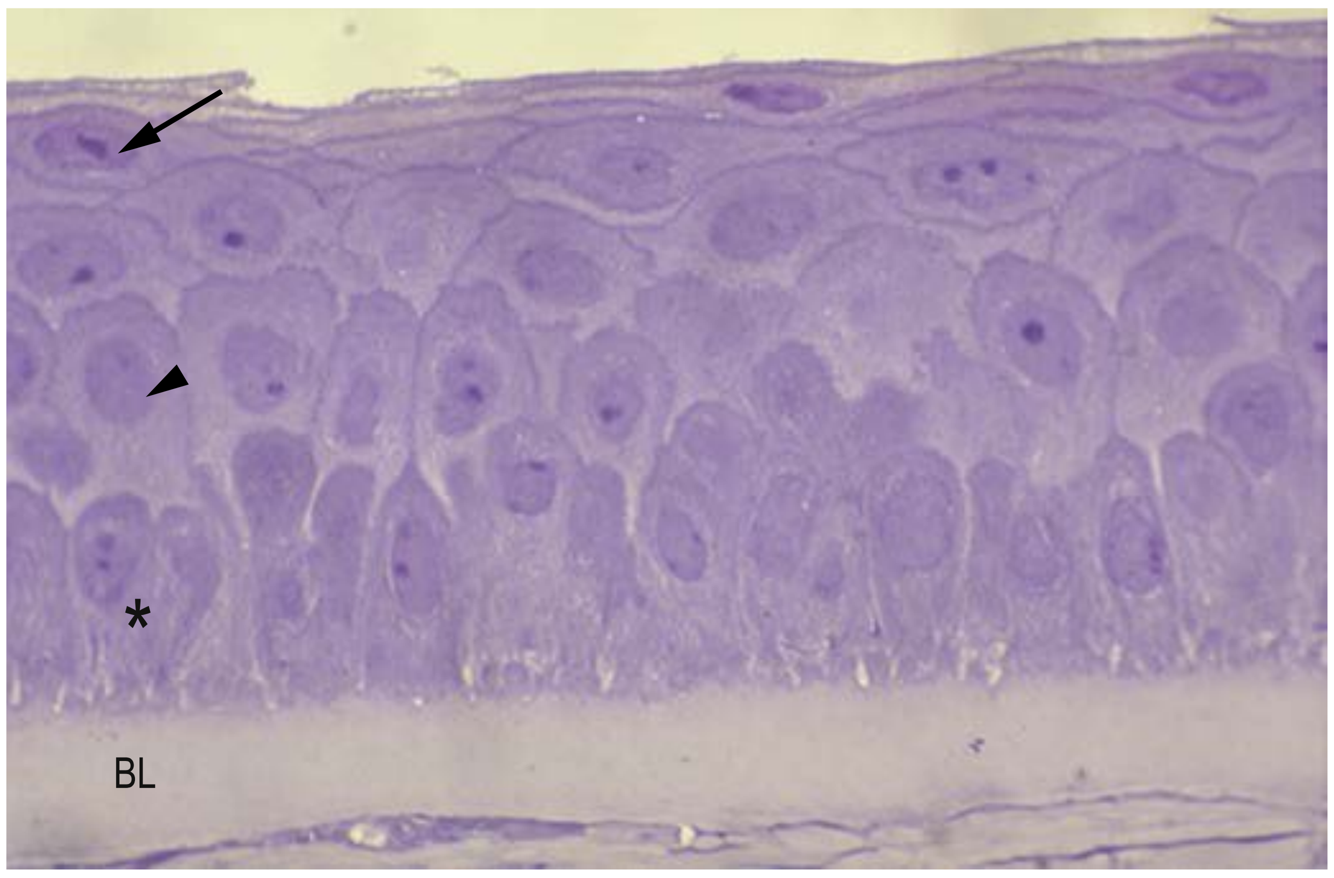

Fig. 2.2 Corneal epithelium (detail). Three cell types are present: basal cells (asterisk), wing cells (arrowhead) and squamous cells (arrow). BL= Bowman's layer.

Basal cells consist of single-layer columnar cells with a vertically oriented oval nucleus. Ultrastructurally, they are similar in appearance to wing cells. The plasma membrane similarly shows pronounced infolding and the cytoplasm contains prominent intermediate filaments. A variety of cell junctions are present including: desmosomes, which mediate adhesion between cells; hemidesmosomes, which are involved in the attachment of basal cells to the underlying stroma; and gap junctions, which allow for intercellular metabolic coupling. Basal cells form the germative layer of the cornea, and mitotic cells are often seen at this level.

Basal Lamina and Bowman's Layer. The basal lamina (basement membrane) is synthesized by basal cells. It varies in thickness between 0.5 and 1 µm, and under the electron microscope can be differentiated into an anterior clear zone (lamina lucida) and a posterior darker zone (lamina densa). The basal lamina is part of a complex adhesion system, which mediates the attachment of the epithelium to the underlying stroma (Fig. 2.3). Hemidesmosomes link the cytoskeleton via a series of anchoring fibrils to anchoring plaques in the anterior stroma. The molecular components of this adhesion complex have been identified and include type VII collagen, integrins, laminin and bullous pemphigoid antigen (Gipson et al., 1987).

Bowman's layer (anterior limiting membrane) varies in thickness between 8 and 14 µm. With the light microscope it appears as an acellular homogeneous zone. Ultrastructurally, it is composed of a randomly oriented array of fine collagen fibrils, which merge with the fibrils of the anterior stroma (Hogan et al., 1971). Fibrils are composed primarily of collagen types I, III and V. Collagen VII, associated with anchoring fibrils, is also present. There is evidence that Bowman's layer is formed and maintained primarily by the epithelium, although its function is unclear. The absence of Bowman's layer from the cornea of most mammals, and the fact that corneas devoid of this layer over the central cornea following photorefractive keratectomy (PRK) apparently function normally, suggest that it is not critical to corneal integrity (Wilson and Hong, 2000).

Stroma. The stroma is approximately 500 µm thick, and accounts for 90% of the thickness of the cornea. It is composed predominantly of collagen fibrils (70% dry weight) embedded in a highly hydrated matrix of proteoglycans. A variety of collagen

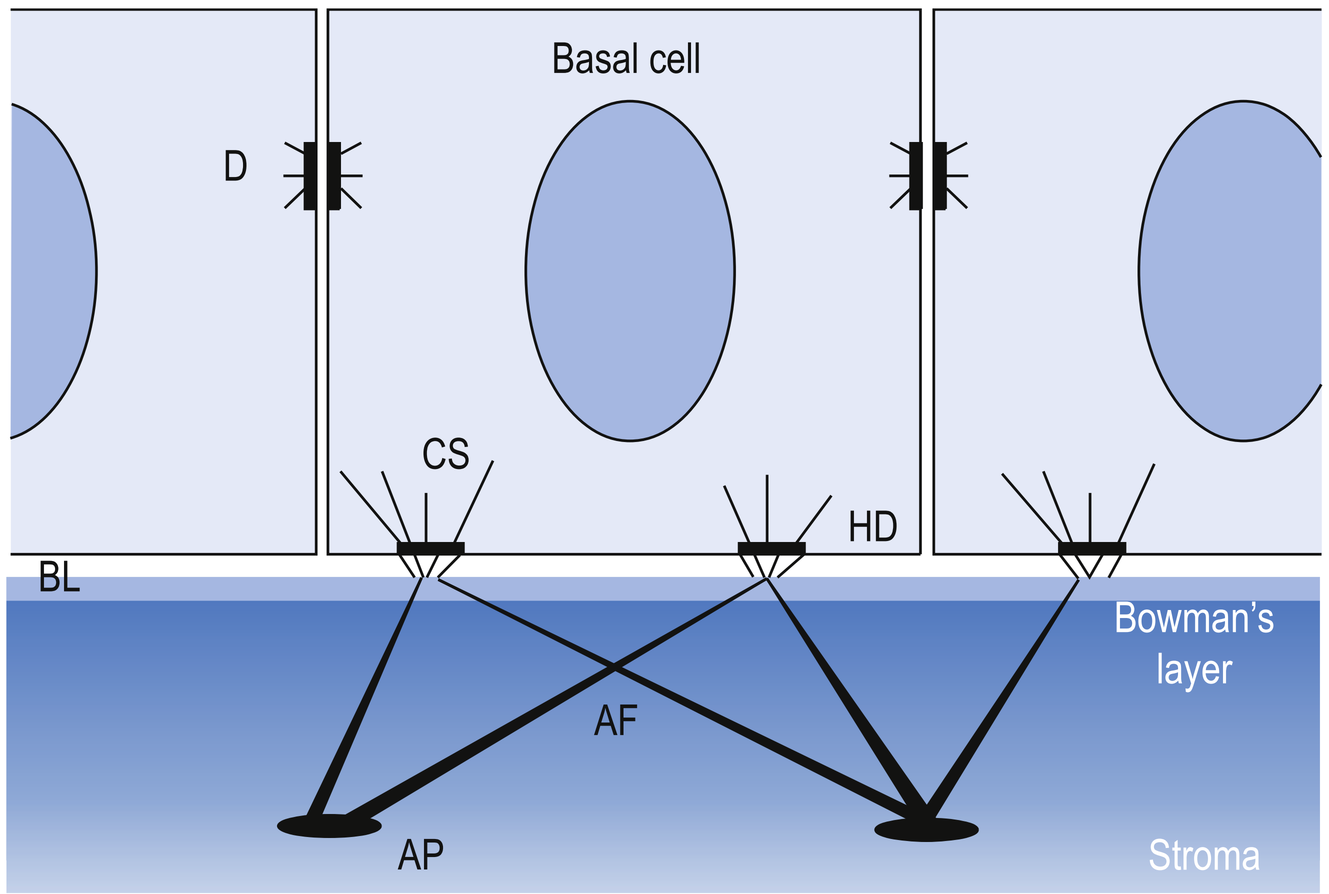

Fig. 2.3 Schematic representation of the adhesion system of the corneal epithelium. Intermediate filaments in the cytoskeleton (CS) are linked through hemidesmosomes (HD) via anchoring fibrils (AF) to anchoring plaques (AP) in the anterior stroma. BL= basal lamina; D= desmosome.

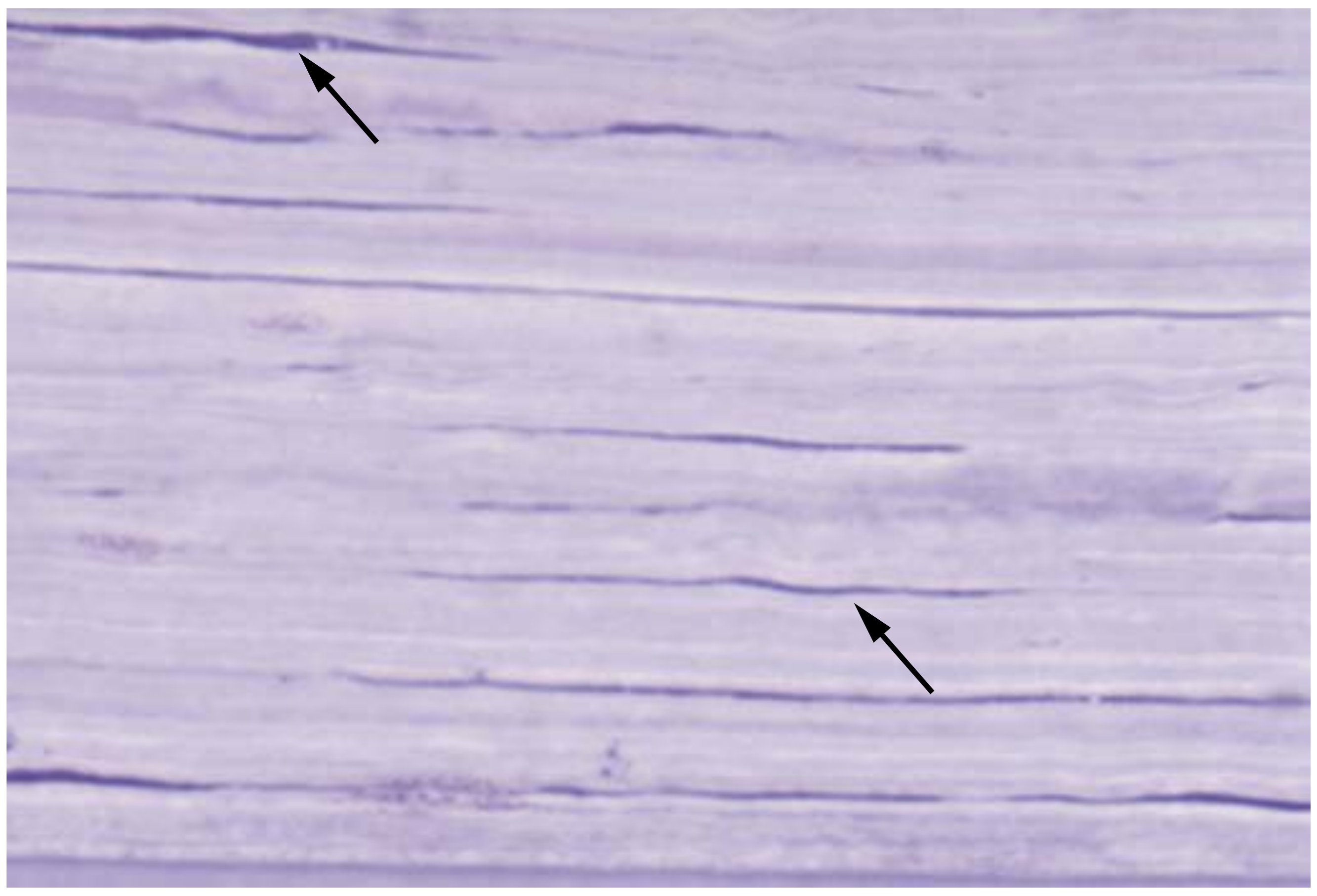

Fig. 2.4 Section through the stroma. Keratocytes (arrowed) are located between lamellae.

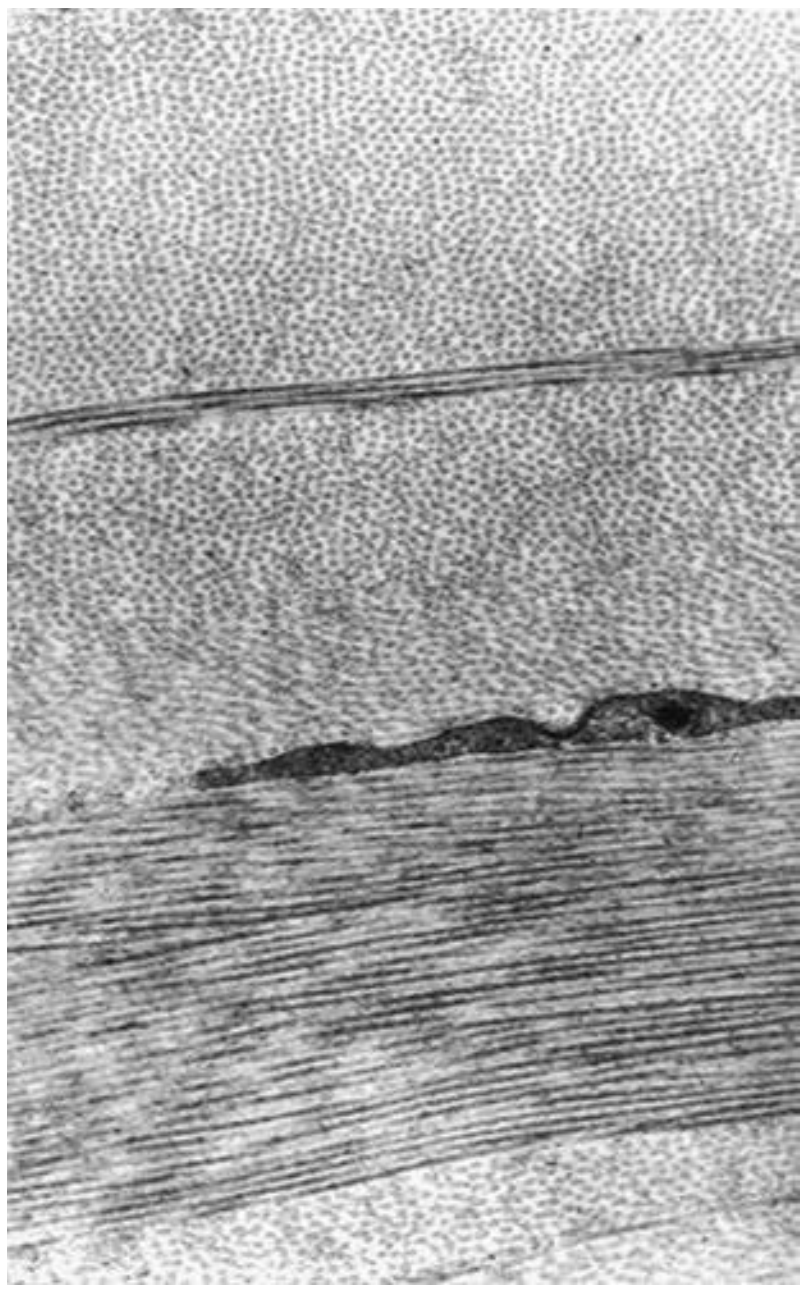

Fig. 2.5 Electron micrograph of stromal lamellae that cross each other approximately at right angles. Note the regular arrangement of collagen fibrils within lamellae.

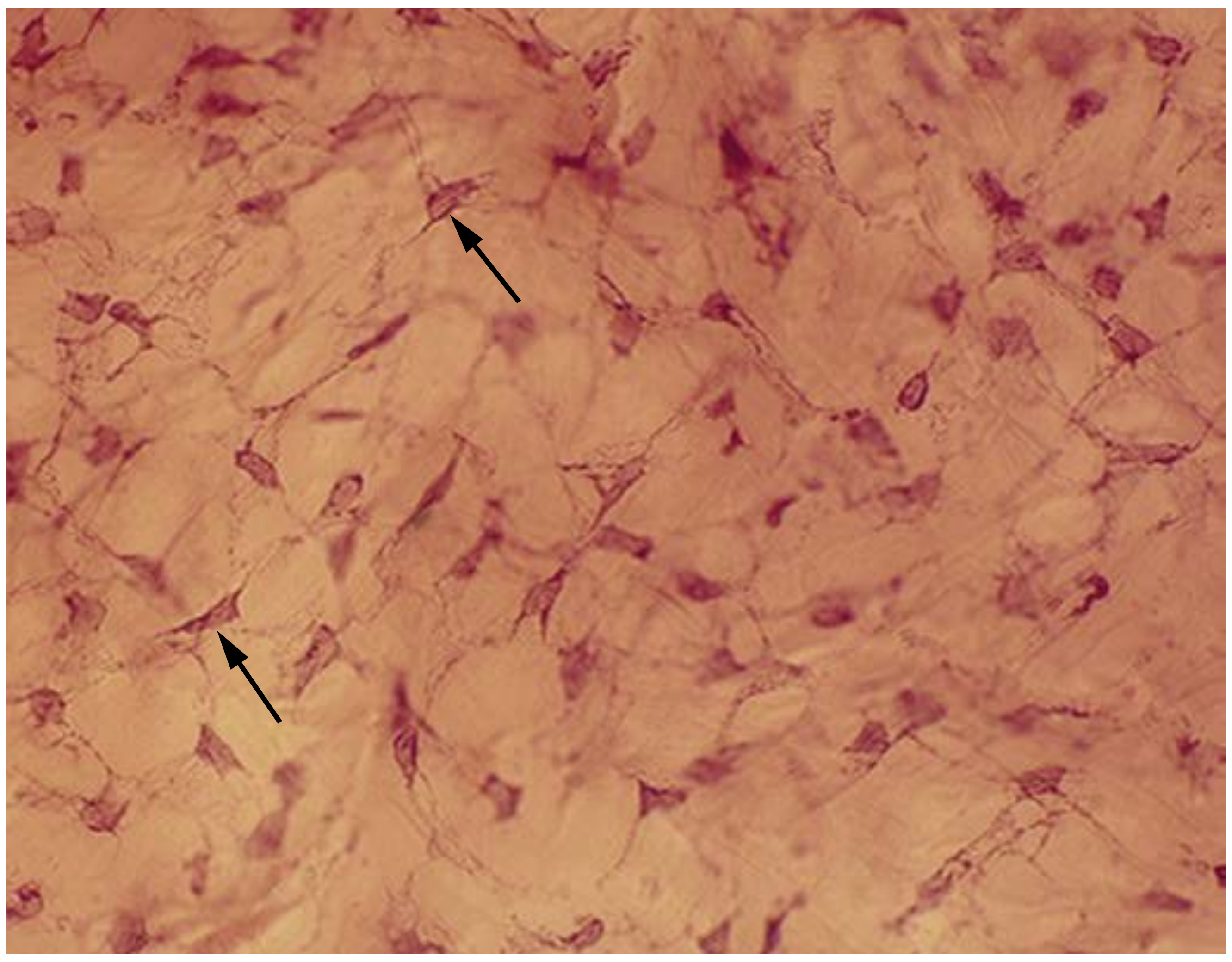

Fig. 2.6 Flat section through the stroma stained with gold chloride. Keratocytes (arrowed) display a stellate appearance.

types have been identified. Type I is the major fibril-forming collagen, with lesser amounts of types III and V. Non-fibril-forming collagens, including types VI and XII, are found in the interfibrillar matrix (Meek and Boote, 2009). A section taken perpendicular to the corneal surface reveals that the collagen fibrils are arranged in 200–250 layers (lamellae) running parallel to the surface (Fig. 2.4). Lamellae are approximately 2 µm thick and 9–260 µm wide, and extend from limbus to limbus. Fibrils of adjacent lamellae make large angles with each other. In the superficial stroma the angles are less than 90°, but fibrils become orthogonal in the deeper stroma (Hogan et al., 1971; Meek and Boote, 2009). This preferred orthogonal orientation gradually changes in favour of circumferentially aligned collagen at the limbus. This particular arrangement of collagen imparts a high tensile strength for corneal protection, which is important given its exposed position. Within lamellae, all collagen fibrils are parallel with uniform size and separation (Fig. 2.5). Accurate physiological measurements of collagen fibre diameter and spacing can be obtained for the hydrated cornea with the aid of X-ray diffraction. Using this technique, the mean fibril diameter in the human cornea is 31 nm, with an interfibrillar spacing of 55 nm (Meek and Leonard, 1993). This narrow fibril diameter and constant separation, which is a characteristic of corneal collagen, are necessary prerequisites for transparency.

The interfibrillar space contains a matrix of proteoglycans (approximately 10% of dry weight). These molecules are highly sulphated, and along with bound chloride ions create a polyanionic stromal interfibrillar matrix that induces osmotic swelling. As well as playing a major role in corneal hydration, collagen–proteoglycan interactions are also thought to be important in determining the size and spatial arrangement of stromal collagen fibrils (Scott, 1991; Quantock and Young, 2008).

Collagen and proteoglycans are maintained by keratocytes. These cells occupy 3–5% of stromal volume and lie between collagen lamellae, flattened in the plane of the cornea (Fig. 2.6). Keratocyte density examined by confocal microscopy and biochemical methods (Møller-Pederson and Ehlers, 1995; Prydal et al., 1998) is non-uniform. Density decreases from superficial to deep stroma (Hollingsworth et al., 2001) and increases from centre to periphery. Keratocytes display a large central nucleus and long slender processes extend from the cell body. Processes from adjacent cells sometimes make tight junctions with each other. Cell organelles are not numerous but the usual complement of organelles, including endoplasmic reticulum, Golgi apparatus and mitochondria, can be observed (Hogan et al., 1971).

Newer lamellar corneal transplantation techniques have been developed that allow selective replacement of the diseased corneal layers. Deep anterior lamellar keratoplasty (DALK), which is increasingly being used to treat keratoconus and corneal scarring, involves replacement of the affected stroma while retaining the host's healthy Descemet's membrane and endothelium. Separation between the posterior stroma and Descemet's / endothelium can be achieved by intrastromal injection of air, viscoelastic or saline. Dua and co-workers performed a histological examination of donor corneas using air bubble separation and claimed to have identified a novel 'pre-Descemet's posterior stromal layer', which was widely publicized (Dua et al.,

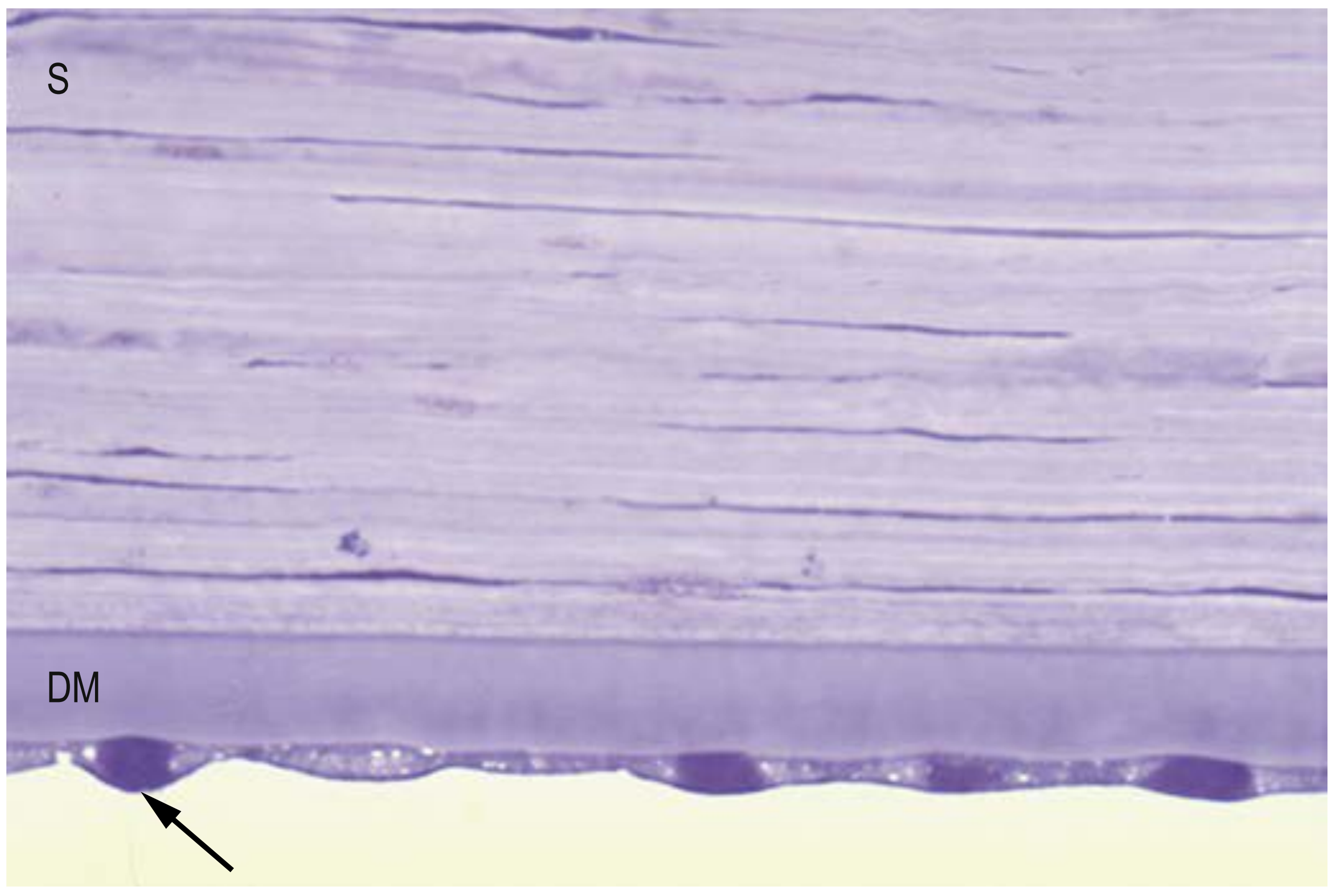

Fig. 2.7 High-powered micrograph of the posterior stroma. Descemet's membrane (DM) is located between the stroma (S) and the endothelium (arrow).

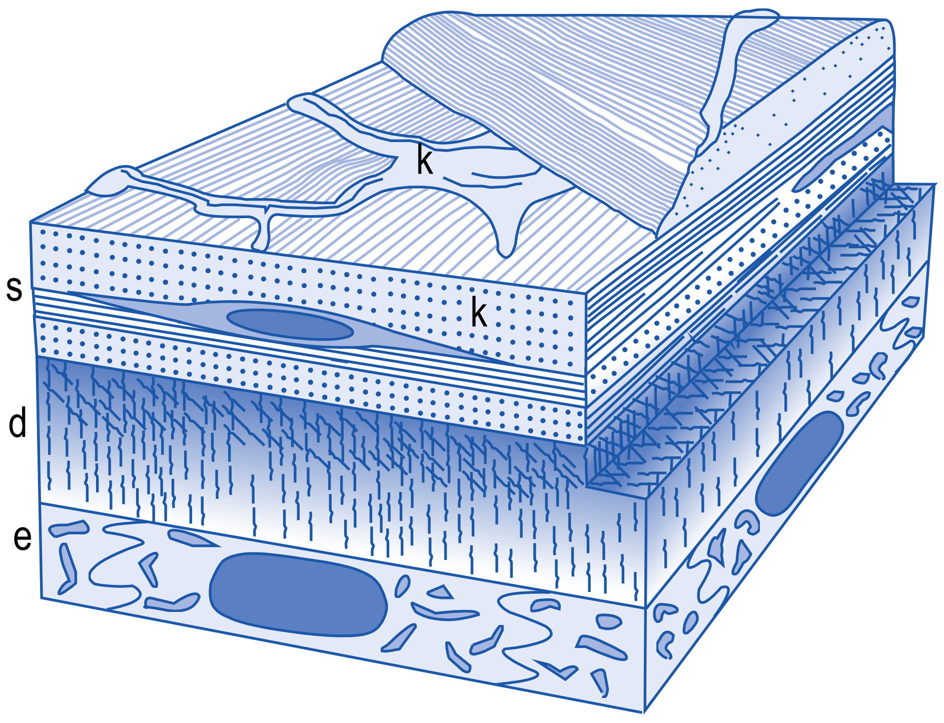

Fig. 2.8 Three-dimensional representation of the posterior cornea showing the endothelium (e), Descemet's membrane (d) and stroma (s). A stromal lamella has been reflected to reveal an intralamellar keratocyte (k).

2013). However, the current consensus amongst corneal experts is that this layer is not sufficiently unique to constitute a new corneal layer (Jester et al., 2013).

Descemet's Membrane. Descemet's membrane is the basement membrane of the corneal endothelium. It lies between the endothelium and the overlying stroma (Fig. 2.7). At birth it is 3–4 µm thick, and increases to a thickness of 10–12 µm in the adult. In the periphery of aged corneas, Descemet's membrane displays periodic sections of thickening, which are known as Hassall–Henle warts. The anterior one-third of Descemet's membrane represents that part produced in fetal life and, under the electron microscope, is characterized by a periodic banded pattern (Fig. 2.8). The posterior two-thirds, which is formed postnatally, has a more homogeneous granular appearance. Descemet's membrane has a unique biochemical composition in contrast with other basement membranes (Lawrenson et al., 1998). The major basement membrane collagen type is type IV, whereas in Descemet's membrane type VIII collagen predominates.

Endothelium. The endothelium is a monolayer of squamous cells that lines the posterior surface of the cornea (Fig. 2.9) and plays a critical role in maintaining corneal transparency (Bonanno, 2012). As it has a limited capacity for mitosis to replace damaged or effete cells, there is a progressive reduction in endothelial cell number with age. At birth the cornea contains a total of approximately 500 000 cells, which represents a mean density of 4500 cells/mm^2. During infancy, cell loss is particularly marked and a 26% reduction occurs in the first year of life (Sherrard et al., 1987). Thereafter the rate of loss progressively declines into old age. Since grafted corneas appear to maintain transparency and functional normality with an endothelial cell density of less than 1000 cells/mm^2, it seems that normal cell density represents a considerable 'physiological reserve' (Klyce and Beuerman, 1998). When viewed en *face*, for example using a specular microscope, the endothelium appears as a mosaic of polygonal (typically hexagonal) cells (Efron et al., 2001). In response to pathology, trauma, age and prolonged contact lens wear, the endothelial mosaic becomes less regular, and shows a greater variation in cell size (polymegethism) and shape (pleomorphism) as cells spread to fill gaps caused by cell loss. Under the electron microscope, the lateral borders of the cells are markedly convoluted and adjacent cells are linked by tight junctions (with less-frequent gap junctions) (Hogan et al., 1971). The complement of organelles seen in endothelial cells reflects their high metabolic activity, with numerous mitochondria and a prominent rough endoplasmic reticulum.

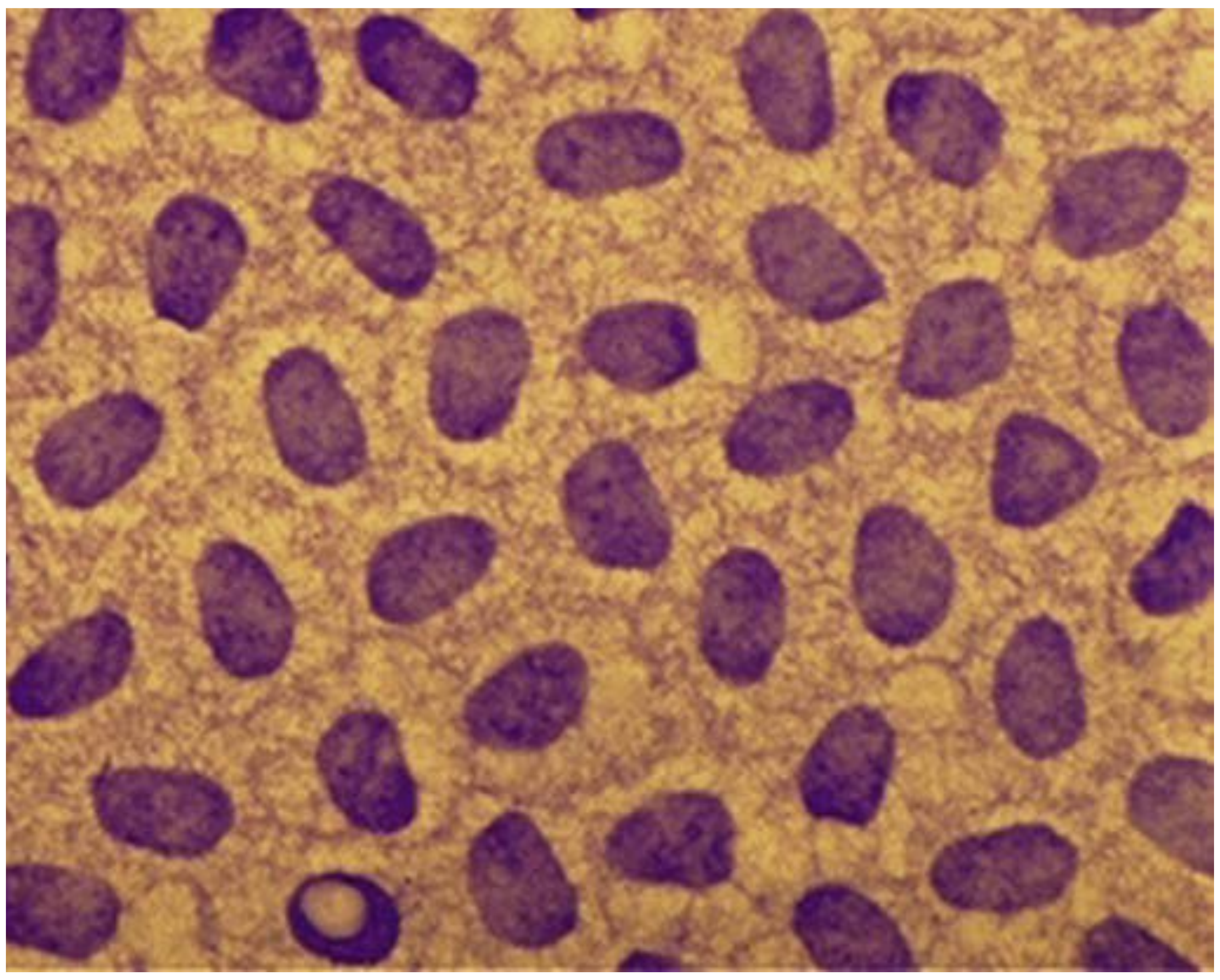

Fig. 2.9 Tangential (flat) section through the corneal endothelium: a single layer of polygonal cells with irregular borders can be observed.

CORNEAL INNERVATION

Source and Distribution of Corneal Nerves

The cornea is the most richly innervated surface tissue in the body. Corneal nerves are responsible for the detection of somatosensory stimuli and play an important role in initiating the blink reflex, wound healing and tear secretion (see Shaheen et al., 2014, for a recent review). The majority of corneal nerves are sensory and derive from the nasociliary branch of the trigeminal nerve (Ruskell and Lawrenson, 1994). There is also evidence for the existence of a modest sympathetic innervation from the superior cervical ganglion (Marfurt and Ellis, 1993). Branches from the nasociliary nerve either pass directly to the eye as long ciliary nerves or traverse the ciliary ganglion, leaving it as short ciliary nerves that enter the eye close to the

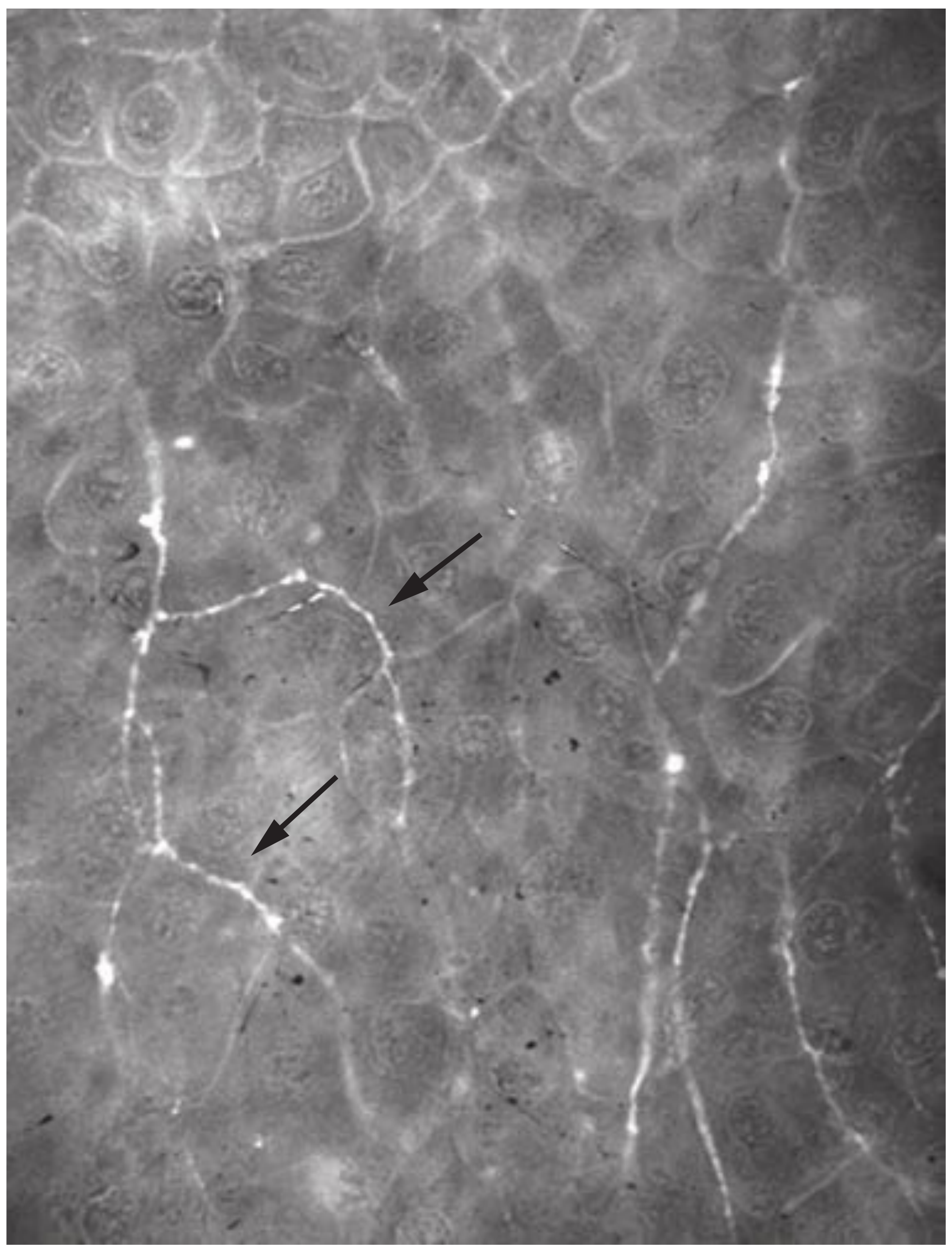

Fig. 2.10 Whole-mount gold chloride-stained preparation of corneal nerves (arrows) located at basal level.

optic nerve. Nerves destined for the cornea travel initially in the suprachoroidal space, before crossing the sclera to advance radially towards the cornea.

Most of the 50–80 precorneal nerve trunks, which contain a mixture of myelinated and unmyelinated fibre bundles, enter the cornea at mid-stromal level. Myelin is soon lost and the unmyelinated nerve fibre bundles divide repeatedly and move anteriorly to form a rich plexiform network in the anterior one-third of the stroma. Axons are particularly dense immediately beneath Bowman's layer, forming an extensive subepithelial plexus (Oliveira-Soto and Efron, 2001). From this plexus, axons pass vertically through Bowman's layer, losing their Schwann cell sheath in the process. Upon entering the epithelium, axons turn through 90° and divide into a series of fine branches that course between basal cells (Fig. 2.10). Some branches pass into the more superficial layers before terminating. The density of nerve terminals is greatest centrally, corresponding to approximately 600 terminals/mm^2, which results in large overlapping receptive fields (Shaheen et al., 2014).

Corneal nerves display a complex neurochemistry. A variety of neurotransmitters and neuromodulators have been identified, including acetylcholine, substance P, and calcitonin gene-related peptide. However, it is unclear how these particular neurochemicals correlate with function (Belmonte et al., 1997).

Functional Considerations

Corneal nerves serve important sensory, reflex and trophic functions. Interest in the sensitivity of the cornea dates back to the 19th century (Lawrenson, 1997), when the pioneering German physiologist von Frey concluded that pain was the only sensation perceived by the cornea. This was consistent with his theory of the specificity of sensory receptors, which maintained that each sensory modality was subserved by a separate anatomically distinct nerve terminal. In his experiments on the cornea, von Frey could elicit only a sensation of pain and, as the cornea contained exclusively free (unspecialized) nerve endings, he concluded that free nerve endings were the exclusive receptors for pain. Although the specificity theory has subsequently been challenged, particularly with respect to its exclusivity, the question as to whether pain is the only sensory modality perceived by the cornea remains.

Modern experiments using carefully controlled corneal stimulation, with a variety of mechanical, chemical and thermal stimuli, have evoked only sensations of irritation or pain. By contrast, electrophysiological studies of corneal afferent neurones have identified neurones that respond to mechanical, thermal and chemical stimulation. However, since the conscious perception of these sensations has not been demonstrated, it is likely that such specificity of modality is lost during central nervous system processing. Electrophysiological recording also allows for the mapping of receptive fields. These are often large and overlapping, which explains the inability of the cornea to localize a stimulus accurately (Belmonte et al., 1997). The sensitivity of the cornea to mechanical stimulation is particularly acute, and acts as a trigger for the protective blink and lacrimal reflexes. Cold receptors may be important in signalling evaporative cooling, which is a major determinant of spontaneous eye blink frequency (Tsubota, 1998).

Corneal afferent fibres also exert important trophic influences. Damage to corneal sensory nerves by surgery, trauma or infection produces neuroparalytic keratitis – a condition that is characterized by progressive epithelial cell loss and oedema. The mechanism of this trophic role is not fully understood, although the release of neuropeptides (e.g. substance P and calcitonin gene-related peptide) may be a factor. Sympathetic nerves also play a role in epithelial maintenance by regulating ion transport processes, and cell proliferation and migration during wound healing.

CORNEAL METABOLISM

Source of Oxygen and Nutrients

In order to perform its vital functions, the cornea requires a constant supply of oxygen and other essential metabolites (e.g. glucose, vitamins and amino acids). However, its avascularity dictates that alternative routes must exist for the provision of its metabolic needs. There are three possibilities: from the perilimbal vasculature, from the tear film or from the aqueous humour. In open-eye conditions the bulk of the oxygen required for the cornea is obtained from the atmosphere via diffusion across the precorneal tear film. Under steady-state conditions it can be assumed that the tears are saturated with oxygen, and therefore at an oxygen tension corresponding to the atmosphere (155 mmHg at sea level). It has been estimated that the oxygen tension of the aqueous humour in the human eye lies between 30 and 40 mmHg (Klyce and Beuerman, 1998).

Experiments using nitrogen-filled goggles or sealed scleral lenses have shown the corneal dependence on tear-side oxygen to avoid oedema and maintain normal function. The reason why the cornea swells during contact lens wear is explained in Fig. 2.11. During eye closure the oxygen level in the tears is in equilibrium with the palpebral vasculature (55 mmHg) (Efron and Carney, 1979).

Significantly, corneal thickness increases by approximately 5% during sleep, and returns to baseline levels within 1 hour of eye opening. It has been suggested that overnight swelling is related to tear film tonicity rather than reduced oxygen

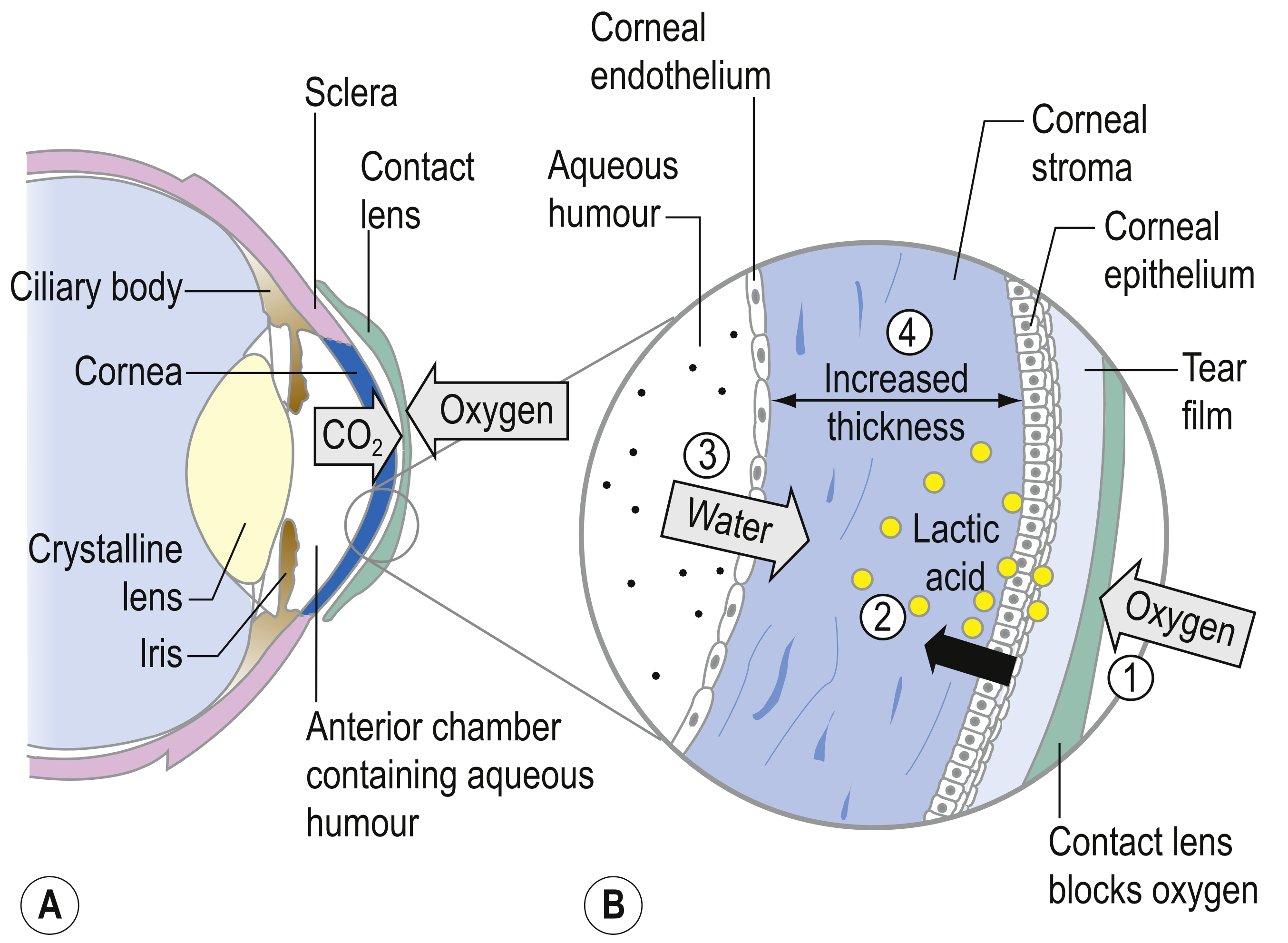

Fig. 2.11 (A) Cross-section of an eye wearing a contact lens, which impedes ingress of oxygen into, and the egress of carbon dioxide from, the cornea. (B) The contact lens blocks oxygen supply to the cornea (1), causing lactic acid to accumulate in the stroma (2). This draws in water (3), leading to stromal oedema (4). (Adapted from Efron, N. (1997). Contact lenses and corneal physiology. Biol. Sci. Rev., 9, 29–31.)

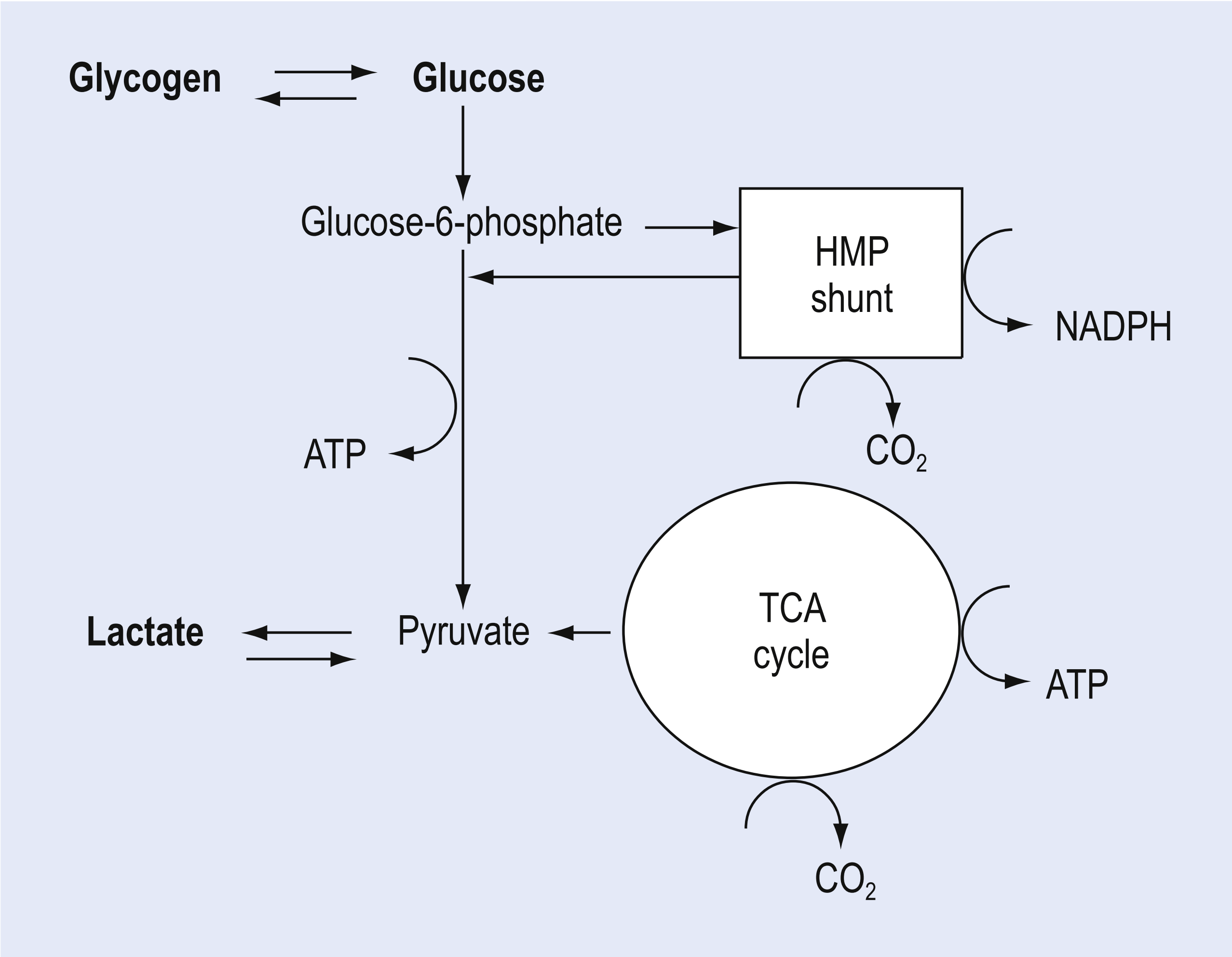

Fig. 2.12 Metabolic pathways present in the cornea. HMP = hexose monophosphate shunt; TCA cycle = tricarboxylic acid (Krebs) cycle; ATP = adenosine triphosphate; NADPH = nicotinamide adenine dinucleotide phosphate (reduced form).

availability (Klyce and Beuerman, 1998). The oxygen flux into the cornea can be measured using polarographic oxygen sensors. It is in the region of 6 $\mu l/cm^2/h$ for the cornea as a whole, although the consumption rate for its composite layers is not equal. Consumption rates have been estimated as 40:39:21 for the epithelium, stroma and endothelium, respectively (Freeman, 1972).

Several lines of evidence indicate that the aqueous humour is the primary source of glucose and essential amino acids for the cornea (Maurice, 1984). The glucose concentration of tears is low compared with that in the aqueous humour, and the insertion of nutrient-impermeable implants into the stroma results in degeneration of the tissue lying anterior to the implant. Although exogenous glucose is primarily utilized, glycogen stores are present in all corneal cells to provide glucose in conditions of metabolic stress.

The role of the perilimbal vasculature in the provision of oxygen and nutrients appears limited and it is likely that it is significant only for the corneal periphery (Maurice, 1984).

Oxidative Metabolism

The cornea derives its energy principally from the oxidative breakdown of carbohydrates (Riley, 1969). Glucose, which is the primary substrate for the generation of adenosine triphosphate (ATP), is catabolized by three metabolic pathways: glycolysis, the tricarboxylic acid (Krebs) cycle and the hexose monophosphate shunt (Fig. 2.12). Anaerobic glycolysis accounts for the majority (85%) of glucose metabolism. In this pathway, glucose is first oxidized to pyruvate and then subsequently reduced to lactate, with a net yield of two molecules of ATP per mole of glucose. The TCA cycle results in a greater energy yield (36 ATP). This pathway is most active in the corneal endothelium, which has the greatest energy requirement.

Metabolic waste products can be potentially damaging if allowed to accumulate. Although carbon dioxide can readily diffuse out of the cornea across its limiting layers, lactate is less easily eliminated. Under normoxic conditions, lactate is able to diffuse slowly across the endothelium into the anterior chamber. However, during periods of hypoxia the proportion of glucose that is metabolized anaerobically increases. The resulting accumulation of lactate causes stromal oedema via an increased osmotic load (Klyce, 1981) and localized tissue acidosis (Klyce and Beuerman, 1998).

The hexose monophosphate shunt (also known as the pentose phosphate shunt) plays an important role in the corneal epithelium (Berman, 1981), where it fulfils several important functions, including the generation of intermediates for biosynthetic reactions and the prevention of oxidative damage by free radicals.

CORNEAL TRANSPARENCY

Under normal conditions the cornea is highly transparent, transmitting more than 90% of incident light. Structurally, the cornea is a typical connective tissue consisting principally of a matrix of collagen and proteoglycans. Under normal circumstances such an arrangement would favour light scatter with consequent loss of transparency. This raises two fundamental questions: how is transparency achieved, and how is it maintained? To begin to answer these questions it is necessary to understand the spatial organization of the stromal matrix and the importance of corneal hydration control.

Stromal Organization

Maurice (1957) explained the transparency of the cornea on the basis of the small diameter and regular separation of the stromal collagen. He suggested that the collagen fibrils of the stroma were disposed in a regular crystalline lattice, and that light scattered by the fibrils is eliminated by destructive interference in all directions other than the forward direction. This situation will hold as long as the axes of the collagen fibrils are arranged in a regular lattice with a separation less than the wavelength of light. It has been suggested, however, that the fibrillar arrangement need not be in a perfect crystal lattice to maintain transparency (Maurice, 1984), although disruption of short-range order between fibrils will lead to increased scatter and a loss of transparency.

The factors involved in the maintenance of collagen fibril size and spatial order are not fully understood. It has been proposed that collagen fibril diameters may be controlled by the incorporation of minor collagens (e.g. type V) into the predominantly type I fibrils (Meek and Leonard, 1993) and that their spatial separation is a function of proteoglycan–collagen interactions (Scott, 1991). Proteoglycans are a family of glycoproteins that consist of a protein core to which are attached sugar chains of repeating disaccharide units termed glycosaminoglycans (GAGs). These molecules are increasingly being recognized as important prerequisites for transparency (Quantock and Young, 2008; Hassell and Birk, 2010). Proteoglycans were originally classified according to their glycosaminoglycan composition; however, current nomenclature groups them into families based on homologous sequences of amino acids in their protein core. Corneal stromal proteoglycans are members of the small leucine-rich family, which are small enough to fit in the space between collagen fibrils. The most prevalent glycosaminoglycan in the cornea is keratan sulphate, which is found in three types of proteoglycan: lumican, keratocan and mimecan (Funderburgh et al., 1991; Funderburgh 2000). The other type of corneal proteoglycan is decorin, which contains a hybrid chondroitin sulphate/dermatan sulphate side chain. Evidence from several sources has shown that lumican and decoran play important roles in regulating collagen fibril diameter and maintaining the spacing between fibrils once formed, which are essential for transparency.

Hydration Control

The state of corneal hydration is another important determinant of corneal transparency (Bonanno 2012). The hydrophilic properties of the stroma are to a large part determined by proteoglycans, which contribute to the fixed negative charge of the stroma and produce a passive gel swelling pressure through electrostatic repulsion (Hodson, 1997). Physiologically, corneal hydration is maintained at approximately 78%. If the cornea is allowed to swell ±5% of this value, it begins to scatter significant quantities of light (Hodson, 1997).

Maintenance of physiological corneal hydration is to a large part dependent on the corneal endothelium, which possesses both a barrier property and a metabolically driven pump. The endothelial barrier to the free passage of molecules from the aqueous humour is formed principally by focal tight junctions between adjacent endothelial cells. However, in contrast to other barrier epithelia, these junctions are of low electrical resistance and allow the passage of ions and small molecules. This leak is offset by the metabolically driven pumping of ions out of the stroma by the endothelium, which maintains a transcellular potential difference (aqueous side negative) to balance stromal swelling pressure (Maurice, 1984). Disruption of this osmotic gradient will result in stromal fluid imbibition.

The specific endothelial ion transport mechanisms responsible for the maintenance of physiological hydration are not fully understood. A simplified model representing our current level of knowledge is represented in Fig. 2.13. There is compelling evidence that a flux of bicarbonate ions is the predominant component of the endothelial ion transport system (Hodson and Miller, 1976). Subsequent studies have identified that Cl^- transporters may also be important in maintaining the pump (Bonanno 2012). The bicarbonate is generated either by a Na^+/HCO_3^- co-transporter located on the basolateral plasma membrane or via the intercellular conversion of carbon dioxide by the enzyme carbonic anhydrase. Bicarbonate leaves the cell via an apical bicarbonate ion channel. The driving force for the bicarbonate flux is generated by a sodium–potassium ATPase that resides on the basolateral endothelial membrane. The energy associated with subsequent sodium re-entry (via Na^+/H^+ and Na^+/HCO_3^- transporters) is coupled to active HCO_3^- flux (Hodson et al., 1991).

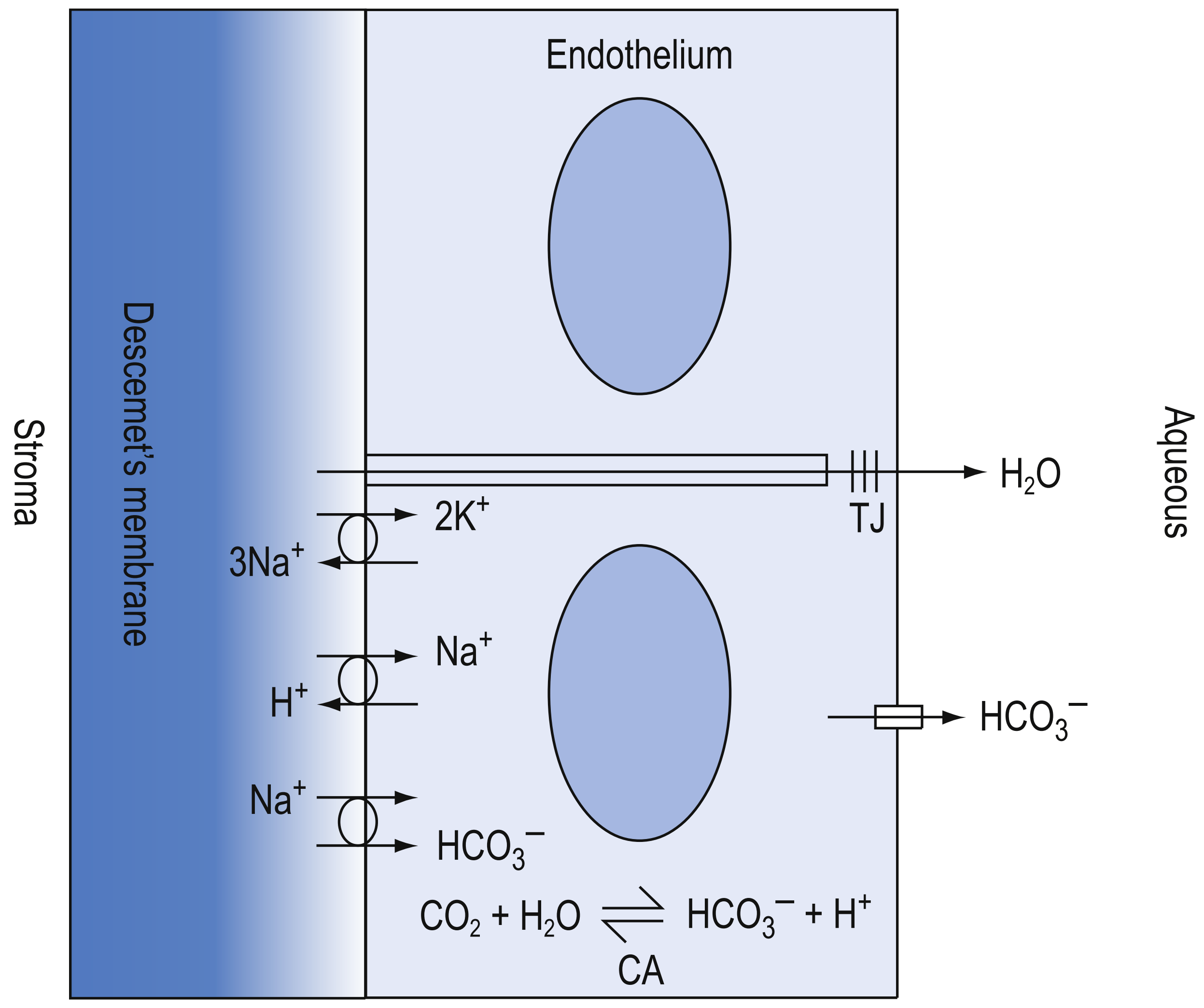

Fig. 2.13 Schematic representation of the corneal endothelial pump. CA = carbonic anhydrase; TJ = tight junction.

The epithelium also contributes to corneal hydration control (Klyce and Beuerman, 1998). The tight junctions between superficial epithelial cells form an effective permeability barrier to ions and polar solutes. For example, the anionic molecule sodium fluorescein does not penetrate an intact epithelium. However, damage to the superficial cells allows fluorescein to enter the epithelium, with resulting corneal staining. In addition to its barrier properties, the epithelium also possesses active ion transport systems for Na^+ and Cl^-. As these pumps contribute to the tonicity of the tear film, it is likely that they are involved in the maintenance of stromal hydration.

Response to Oedema

When corneas swell, light scattering increases, with an ensued transparency loss due to the disruption of the regular collagen matrix. The collagen fibrils themselves swell very little and most of the additional water goes into the interfibrillar spaces. Transmission electron micrographs of oedematous corneas show fibril aggregation, with the result that large areas are devoid of collagen fibrils (Stiemke et al., 1995). There is evidence that collagen aggregation occurs as a result of loss of GAGs, which previously had maintained fibre separation (Stiemke et al., 1995).

CORNEAL EPITHELIAL WOUND HEALING

A smooth and intact corneal epithelium is necessary in order for the cornea to maintain clear vision. However, due to its exposed position the cornea is potentially vulnerable to a variety of external insults. It possesses several protective mechanisms to avoid injury, but if tissue damage occurs it is capable of an effective wound-healing response (Gipson and Inatomi, 1995; Nishida and Tanaka, 1996). Corneal epithelial repair is a complex process involving an orchestrated interaction between cells and extracellular matrix, which is coordinated by a variety of growth factors. The process can be divided into three phases: (1) initial covering of the denuded area by cell migration, (2) cell proliferation to replace lost cells and (3) epithelial differentiation to re-form the normal stratified epithelial architecture.

Following a full-thickness epithelial defect, fibronectin, an adhesive glycoprotein, is synthesized and covers the surface of the bared stroma where it serves as a temporary matrix for cell migration. The adhesion between fibronectin and the epithelium is mediated by integrin–matrix interactions (integrins are a family of cell surface receptors that bind to certain extracellular matrix proteins). Several growth factors have been implicated in the control of the wound-healing response, including epidermal growth factor, transforming growth factor beta, platelet-derived growth factor and fibroblast growth factor (Gipson and Inatomi, 1995). Growth factors, which are produced by a variety of sources (e.g. ocular surface epithelia and the lacrimal gland), are able to regulate the process of epithelial migration, proliferation and differentiation. There is evidence that epithelial–stromal interactions play an important role in corneal wound healing (Wilson, 2000). Epithelial injury triggers keratocyte apoptosis (programmed cell death) in the anterior stroma, via the release of apoptosis-inducing cytokines from epithelial cells. Keratocyte apoptosis subsequently triggers a wound-healing cascade, which influences epithelial repair.

Regeneration of the corneal epithelium is highly dependent on the integrity of the limbus (Lavker et al., 2004). Cumulative evidence indicates that a proportion of limbal basal epithelial cells possess the properties of stem cells, which are ultimately responsible for corneal epithelial replacement. Stem cells have several unique characteristics: they are poorly differentiated, long lived and have a high capacity for self-renewal. When these cells divide, one of the daughter cells replenishes the stem cell pool, whilst the other is destined to undergo further cell divisions before differentiating. Such a cell is referred to as a transient amplifying cell. Transient amplifying cells undergo several rounds of cell division before fully differentiating. These cells play an important role in epithelial wound healing, where their proliferative capacity is increased by shortening cycle times and increasing the number of times that the transient amplifying cells can divide before maturation.

The Ocular Adnexa

The ocular adnexa are those structures that support and protect the eye, and include the eyelids, conjunctiva and lacrimal system. They play an important role in the formation of the preocular tear film and collectively defend the eye against antigenic challenge.

EYELIDS

The eyelids are two mobile folds of skin that perform several important functions: they act as occluders that shield the eyes from excessive light, and through their reflex closure they afford protection against injury. The lids also form a precorneal tear film of uniform thickness during the upturn phase of each blink. The action of blinking is also important for tear drainage.

Gross Anatomy

The eyelids are joined at their extremities, termed 'the canthi', and when the eye is open, an elliptical space, the palpebral fissure, is formed between the lid margins. In the adult, the length of the fissure is approximately 30–31 mm, with a vertical height of 10–11 mm. In the primary position, the upper lid, which is the larger and more mobile of the two, typically covers approximately the upper third of the cornea, whilst the lower lid is level with the inferior corneal limbus (Fig. 2.14). Important differences in eyelid anatomy exist between Asian and Caucasian eyes (Saonanon, 2014). The most obvious feature of the Asian eye is the absent or very low lid fold and fuller upper eyelid.

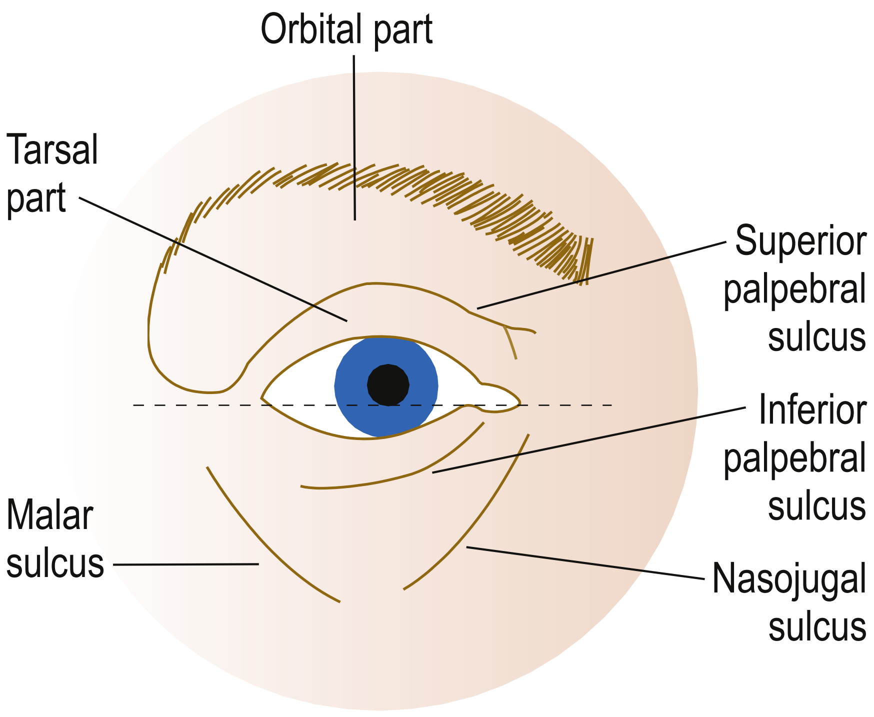

Fig. 2.14 Surface anatomy of the eyelids. (Adapted from Bron, A. J., Tripathi, R. C. & Tripathi, B. (1997). Wolff's Anatomy of the Eye and Orbit (8th ed.). London: Chapman and Hall.)

The eyelid margins are about 2 mm thick from front to back. The posterior quarter consists of conjunctival mucosa and the anterior three-quarters is skin. The junction between the two is referred to as the mucocutaneous junction. There has recently been a renewed interest in the marginal zone of the human eyelid, with the identification of the role of the inner lid border, termed the 'lid-wiper' owing to the analogy to a windscreen wiper, in the distribution of the tear film (Knop et al., 2011a, 2012). Two or three rows of eyelashes (cilia) arise from the anterior border of the lid margins. These are longer and more numerous in the upper lid. The lashes receive a rich sensory nerve supply, and their sensitivity provides an effective alerting mechanism.

The meibomian (tarsal) gland orifices emerge just anterior to the mucocutaneous junction (Fig. 2.15). About 30–40 glands open onto the upper margin, and slightly fewer (20–40) onto the lower. On eversion of the lids the yellowish meibomian acini are visible as yellow clusters through the tarsal conjunctiva (Bron et al., 1991; Knop et al., 2011b). Meibomian glands can be more clearly visualized using infrared meibography, and instruments that use this method are now commercially available (Srinivasan et al., 2012) (Fig. 2.16). At the medial angle, the eyelid margins enclose a triangular space – the lacus lacrimalis – which contains the plica semilunaris and the caruncle. Lacrimal papillae are small elevations located 5–6 mm from the medial canthal angle, which contains a small aperture (punctum) that is the opening to the lacrimal drainage system.

Muscles of the Eyelids

Movements of the eyelids are governed by the coordinated action of several muscles.

Orbicularis Oculi. The orbicularis oculi is the sphincter muscle of the eyelids, and can anatomically be divided into two main divisions: the palpebral and the orbital (Fig. 2.17). Fibres of the palpebral division arise from the medial palpebral ligament and arc across the eyelids in a series of half-ellipses, meeting at the lateral canthus to form a lateral raphe. The lateral palpebral

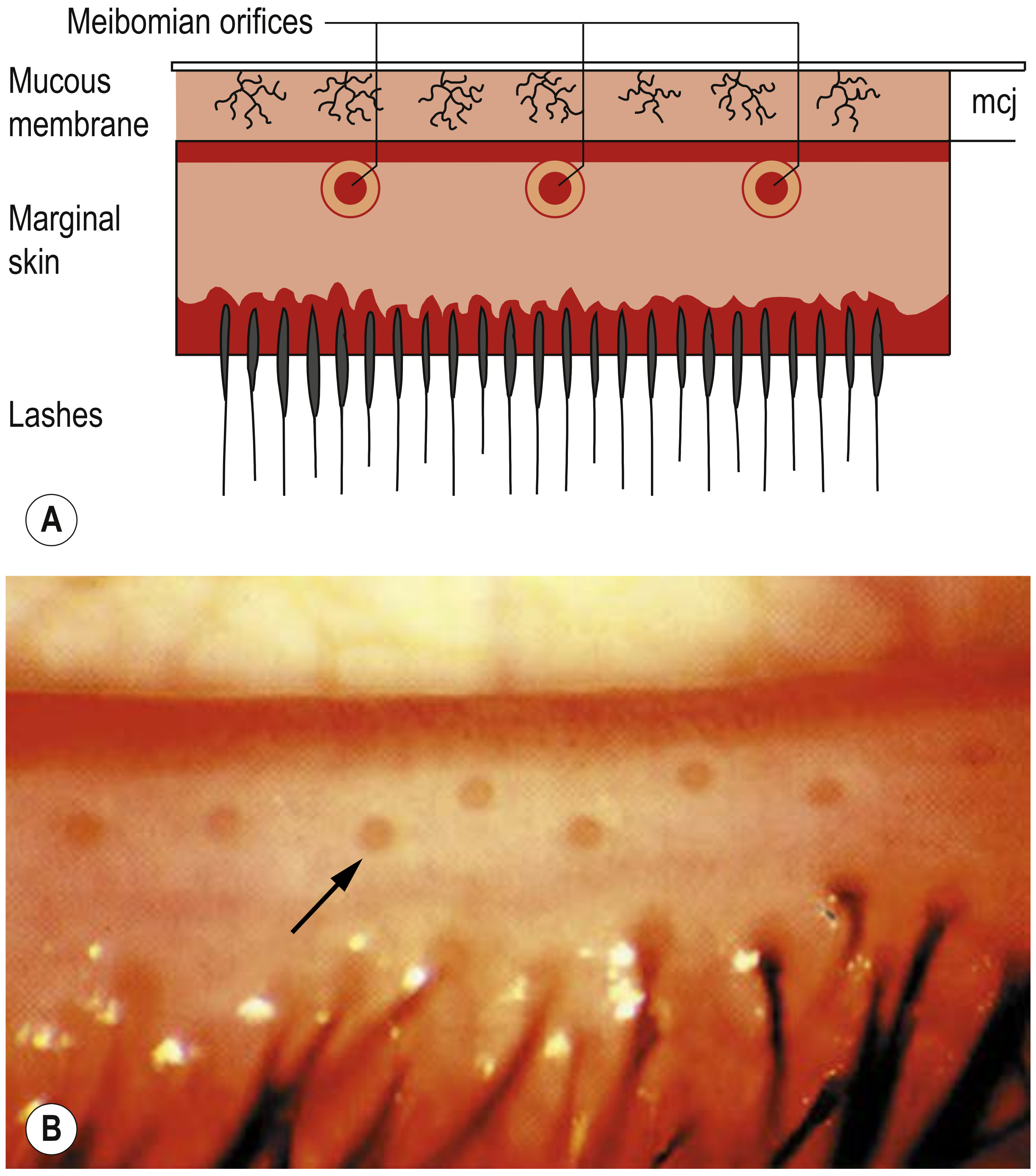

Fig. 2.15 (A) Schematic representation of the eyelid margin. mcj = mucocutaneous junction. (B) Gross appearance of the eyelid margin. Openings of the meibomian glands are clearly visible (arrow). (Adapted from Bron, A. J., Tripathi, R. C. & Tripathi, B. (1997). Wolff's Anatomy of the Eye and Orbit (8th ed.). London: Chapman and Hall.)

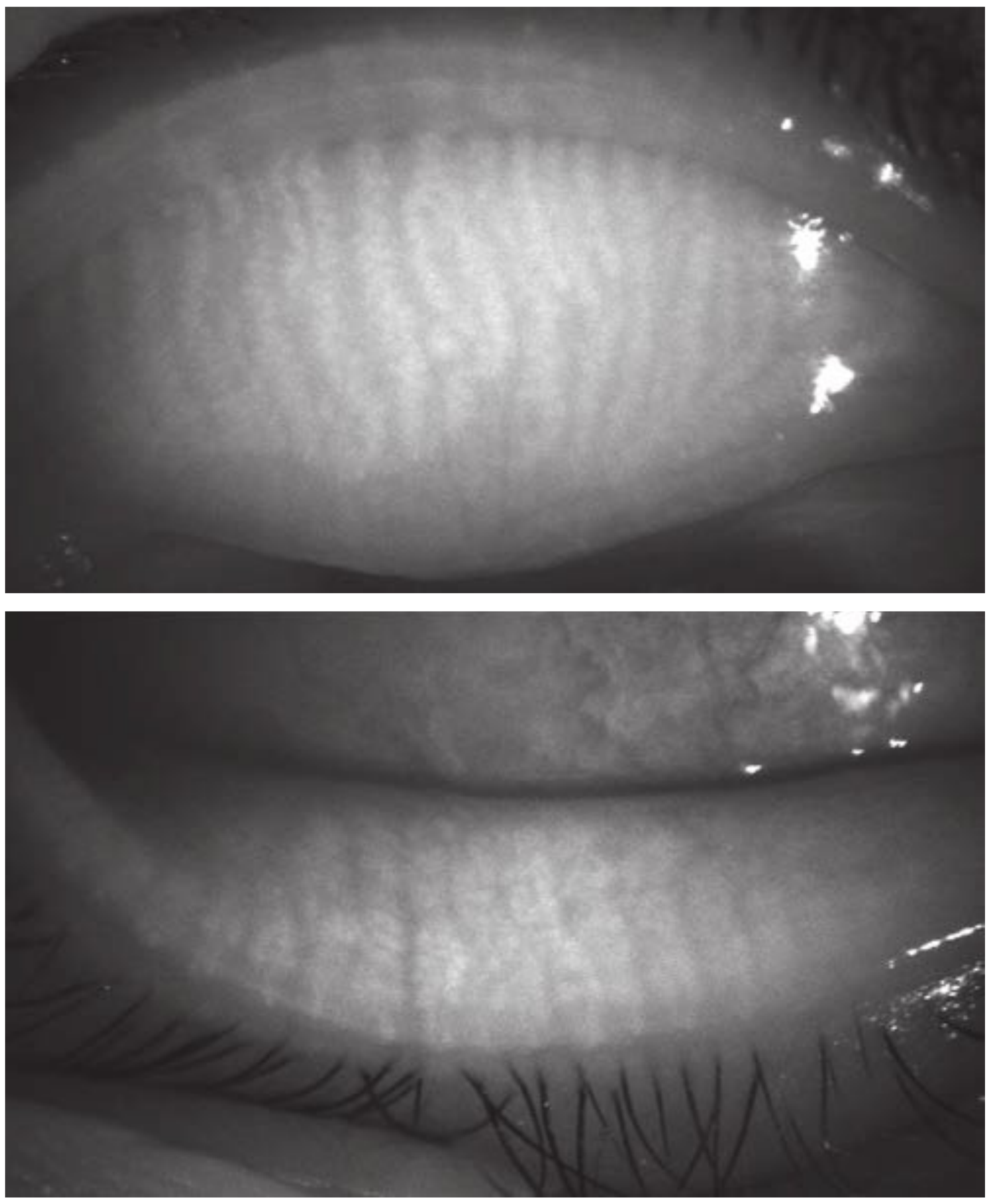

Fig. 2.16 Normal meibomian glands of the upper tarsus (top) and lower tarsus (bottom) of a 38-year-old woman, imaged using non-invasive infrared meibography. (Image courtesy of Reiko Arita.)

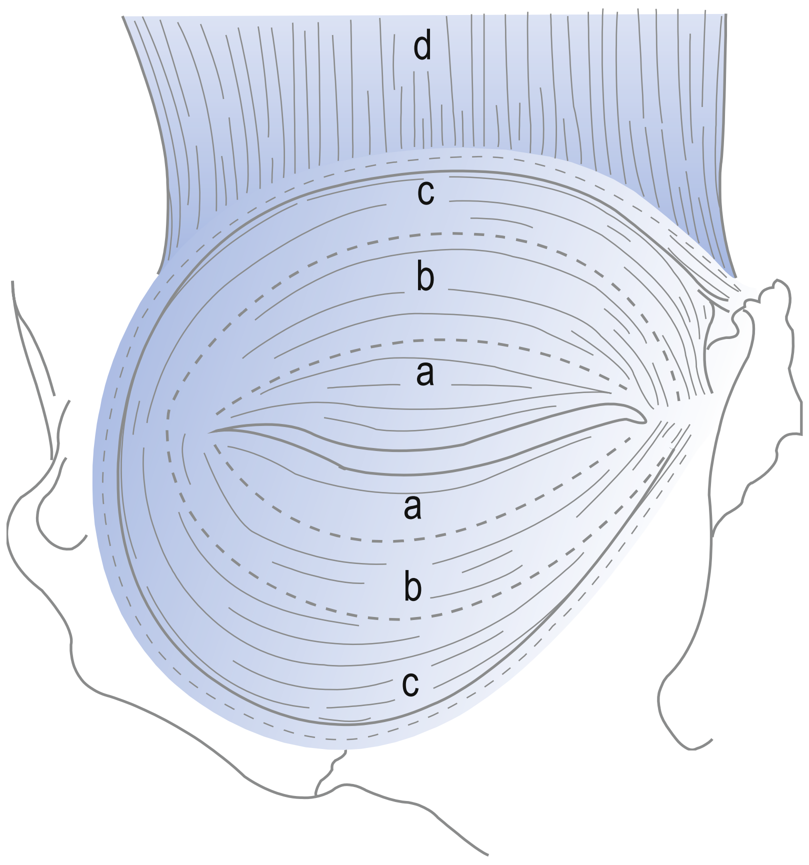

Fig. 2.17 Schematic representation of the divisions of the orbicularis oculi and the frontalis. a = pretarsal; b = preseptal; c = orbital; d = frontalis. (Adapted from Bron, A. J., Tripathi, R. C. & Tripathi, B. (1997). Wolff's Anatomy of the Eye and Orbit (8th ed.). London: Chapman and Hall.)

ligament also acts as an anchor point. The palpebral division can be further subdivided into marginal, pretarsal and preseptal parts. The marginal part (pars ciliaris), which is also known as Riolans muscle, is responsible for maintaining the apposition of the lid to the cornea during lid closure. A third part of the muscle (pars lacrimalis) is closely associated with the lacrimal outflow pathway. The pars lacrimalis (also known as Horner's muscle) encloses the canaliculi and provides attachments to the lacrimal sac and its associated fascia.

The orbital part of the orbicularis oculi lies outside the palpebral division and extends for some distance beyond the orbital margins. Muscle fibres arise predominantly from bone at the medial orbital rim and appear to sweep around the lids without interruption as a series of complete ellipses. However, studies have shown that the muscle fibres of the orbital and palpebral division of the orbicularis are relatively short (0.4–2.1 mm) and overlapping (Lander et al., 1996). The regional divisions of the orbicularis also show a functional distinction. The action of the palpebral part of the muscle is to produce the reflex or voluntary closure of the lids during blinking. Contraction of the orbital division produces the forcible closure of the lids that occurs in sneezing or in response to a painful stimulus.

Levator Palpebrae Superioris. The levator palpebrae superioris is primarily responsible for elevating the upper lid during blinking and for maintaining an open palpebral aperture. The levator palpebrae arises from the lesser wing of the sphenoid, above and anterior to the optic canal, and runs forward along the roof of the orbit above the superior rectus before terminating anteriorly in a fan-shaped tendon (aponeurosis). Some fibres are attached to the anterior surface of the tarsal plate, whilst the remainder pass between fascicles of the orbicularis (Fig. 2.18). The superior palpebral sulcus forms at the upper border of the attachment to the orbicularis.

Superior and Inferior Tarsal Muscles (of Müller). These smooth muscles arise from the lower border of the levator in the upper lid and the inferior rectus in the lower lid, and insert into the orbital margins of the tarsal plates. The role of the superior tarsal muscle is to assist the levator in maintaining the width of the palpebral aperture. A mild degree of ptosis results from damage to its sympathetic nerve supply (Horner's syndrome).

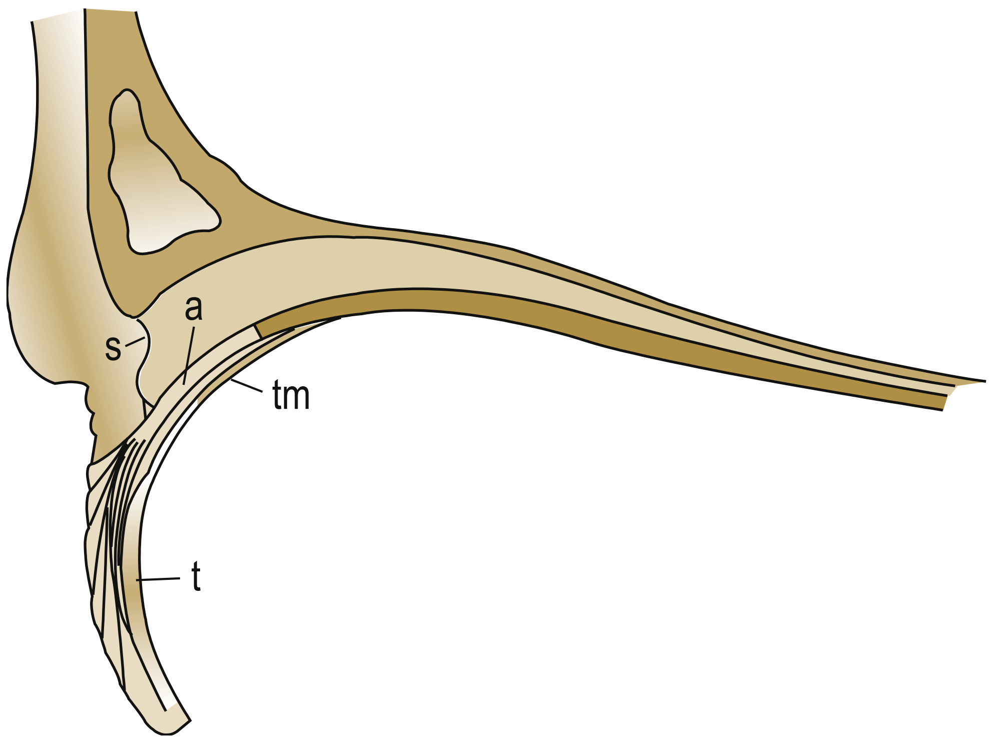

Fig. 2.18 Diagram showing the relations of the levator palpebrae superioris. a = levator aponeurosis; tm = superior tarsal muscle (of Müller); t = tarsal plate; s = orbital septum. (Adapted from Gray, H., Bannister, L. H., Berry, M. M. & Williams, P. L. (1995) Gray's Anatomy: The Anatomical Basis of Medicine and Surgery (38th ed.). Edinburgh: Churchill Livingstone.)

Control of Eyelid Movements

Movements of the eyelids occur through the coordinated action of several muscles – the levator palpebrae, tarsal muscles, the orbicularis oculi and the frontalis. The elevation of the upper lid and the control of its vertical position are mediated principally by the levator. In vertical gaze, lid position and eye movements are closely linked. During elevation the state of contraction of the levator is varied to maximize visibility. In extreme upgaze, lid retraction is augmented by the action of the frontalis, which elevates the eyebrows. In downgaze, coordinated lid movements similarly occur through levator relaxation. In periodic and reflex blinks, the levator is spontaneously inhibited prior to orbicularis contraction in lid closure. Similarly, in lid opening the orbicularis relaxes, followed by contraction of the levator. Spontaneous eye-blink activity is influenced by both central and peripheral factors (Tsubota, 1998).

Compared with the upper lid, the lower lid is relatively immobile and has no counterpart to the levator palpebrae. The depression of the lower lid that occurs in downgaze is due to the attachment of the sheaths of the inferior oblique and inferior rectus muscles to the tarsal plate via a fibrous extension.

Microscopic Anatomy

The histological appearance of the upper and lower lids is similar, and in sagittal section the following six tissue layers can be resolved: skin, subcutaneous connective tissue, muscle layer, submuscular connective tissue, tarsal plate and palpebral conjunctiva (Fig. 2.19).

The eyelid skin is thin and very elastic. It is continuous with the palpebral conjunctiva at the lid margin, and keratinization is maintained up to this mucocutaneous junction. The subcutaneous connective tissue is composed of a loose areolar tissue and contains hair follicles and associated glands. The muscle layer consists of striated muscle fibres of the orbicularis oculi, which are arranged in bundles (fascicles) separated by connective tissue. The orbicularis extends throughout the lid. The marginal part of the muscle (Riolan's muscle) is separated from the pretarsal portion by connective tissue that contains the eyelash follicles. The loose submuscular connective tissue layer lies between the orbicularis and the tarsal plate and contains the major nerves and vessels of the lid.

The tarsal plates (tarsi) are composed of dense fibrous connective tissue and provide support and determine lid shape. They are anchored to the orbital margins by the medial and lateral palpebral ligaments. Each tarsus is approximately 25 mm long and 1–2 mm thick. The upper tarsus is semioval with a height of 11 mm at its midpoint, whereas the inferior tarsus is narrower (4 mm in height). The posterior surface of the eyelid is lined by the palpebral conjunctiva, which is firmly adherent to the underlying tarsal plate.

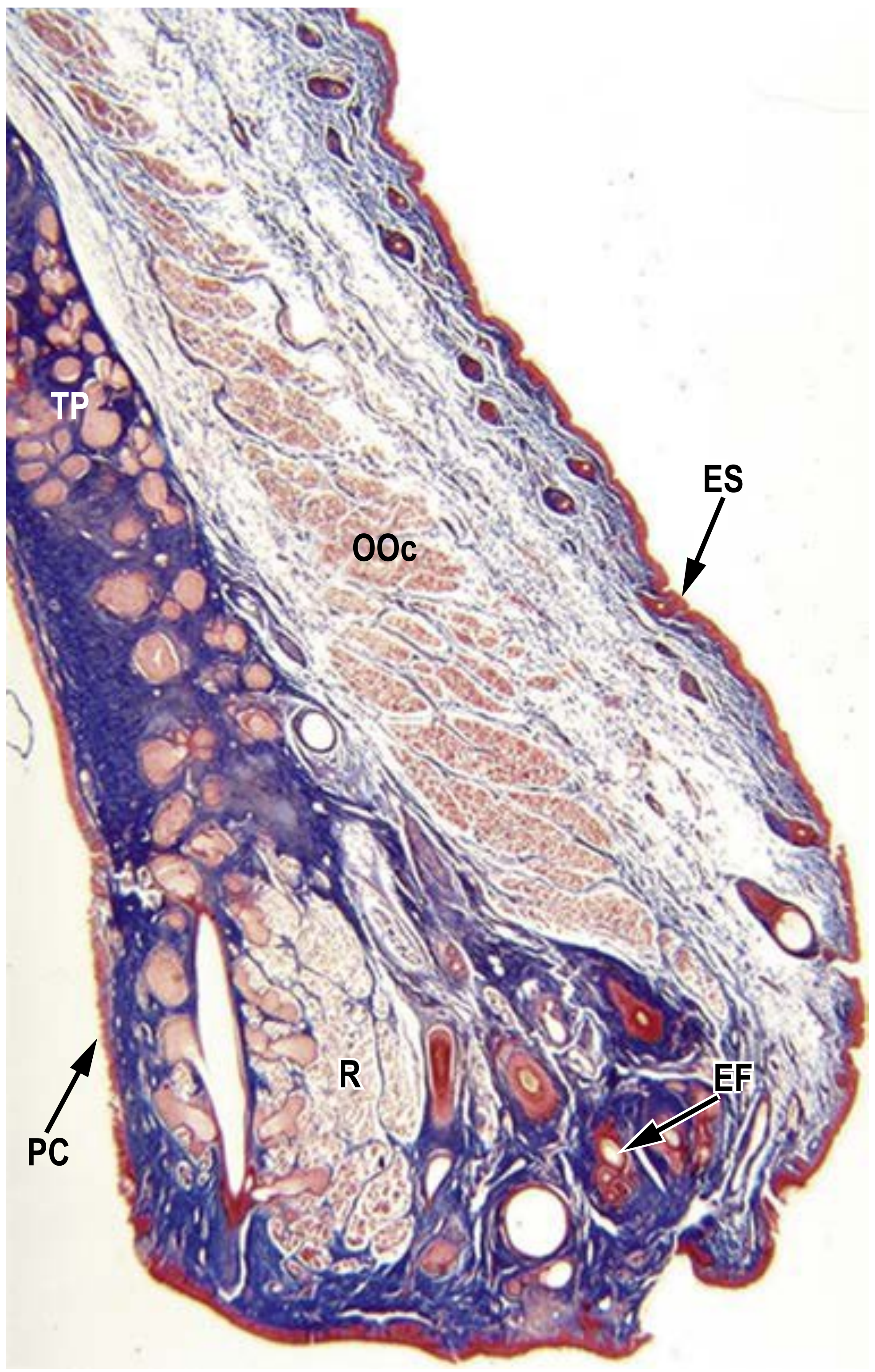

Fig. 2.19 Sagittal section through the upper lid. TP = tarsal plate; OOc = orbicularis oculi; R = Riolan's muscle; EF = eyelash follicles; PC = palpebral conjunctiva; ES = eyelid surface.

Glands of the Eyelids

Meibomian Glands. The tarsal plates contain the acini and ducts of the meibomian (tarsal) glands. Ducts are vertically oriented with respect to the lid margins, with multiple secretory acini that open laterally onto each duct. The glands occupy nearly the full length and width of each tarsus, and are fewer and shorter in the lower lid. Histologically, the acini are lined by a layer of undifferentiated basal cells that divide, and cells are displaced from the basement membrane. As they progress towards the duct they gradually enlarge and develop lipid droplets in their cytoplasm (Fig. 2.20). Ultimately, cell membranes rupture and cellular debris, together with the lipid product, is discharged into the duct.

The stimulus for meibomian gland secretion is unclear. Although a modest autonomic innervation of the meibomian glands has been demonstrated, there is still some doubt regarding a neuromodulation of glandular secretion; it is likely that the principal control of the glands is hormonal, and both androgens and oestrogens have been shown to regulate meibomian secretion (Sullivan et al., 2000; Knop et al., 2011b). A long ductal system carries the secretion to the lid margin, and the compressive action of the palpebral division of the orbicularis oculi on the meibomian ducts facilitates the flow of lipid and its eventual delivery onto the lid margins.

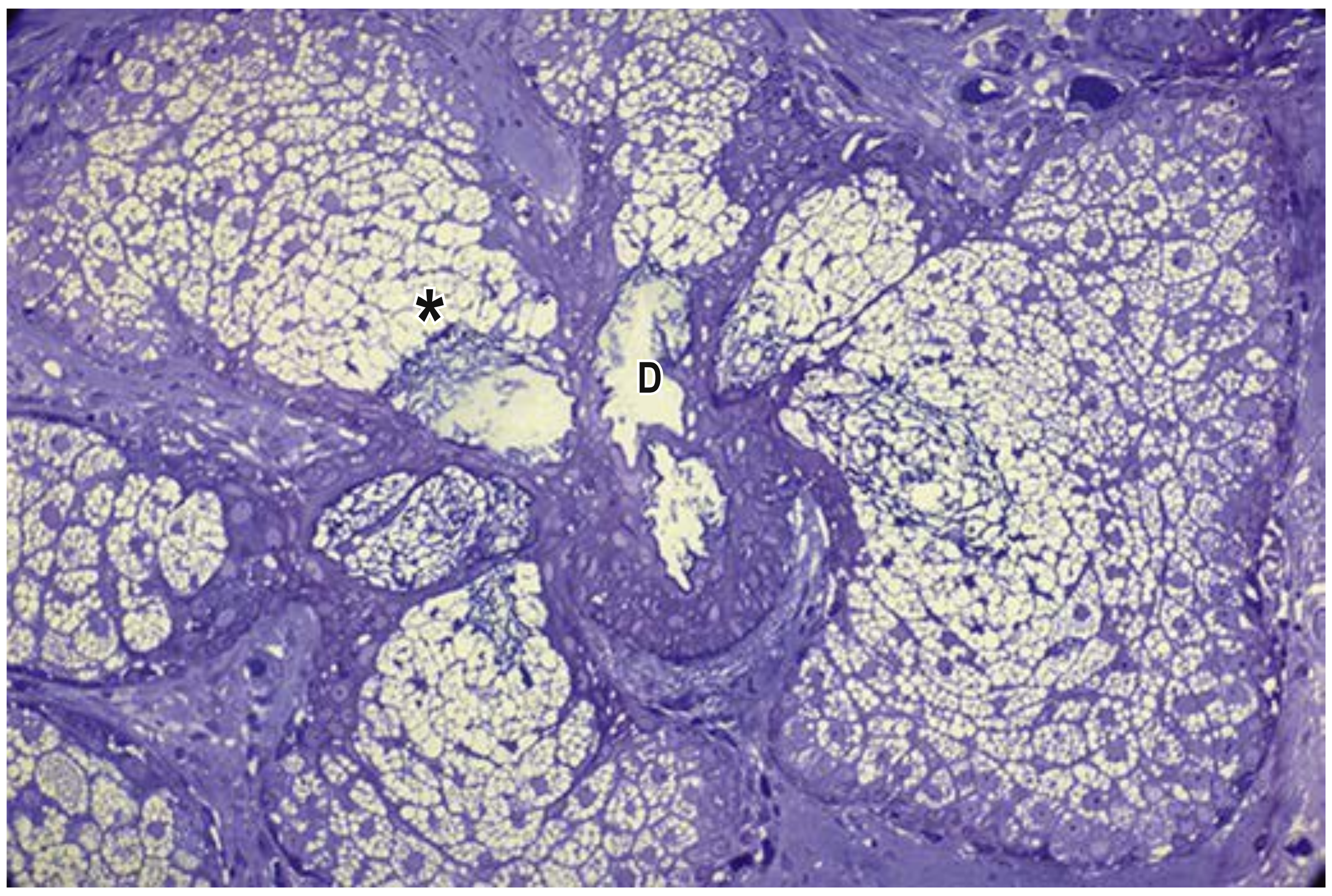

Fig. 2.20 Histological section showing meibomian gland acini. Secretory cells degenerate (asterisk) as they approach the duct (D).

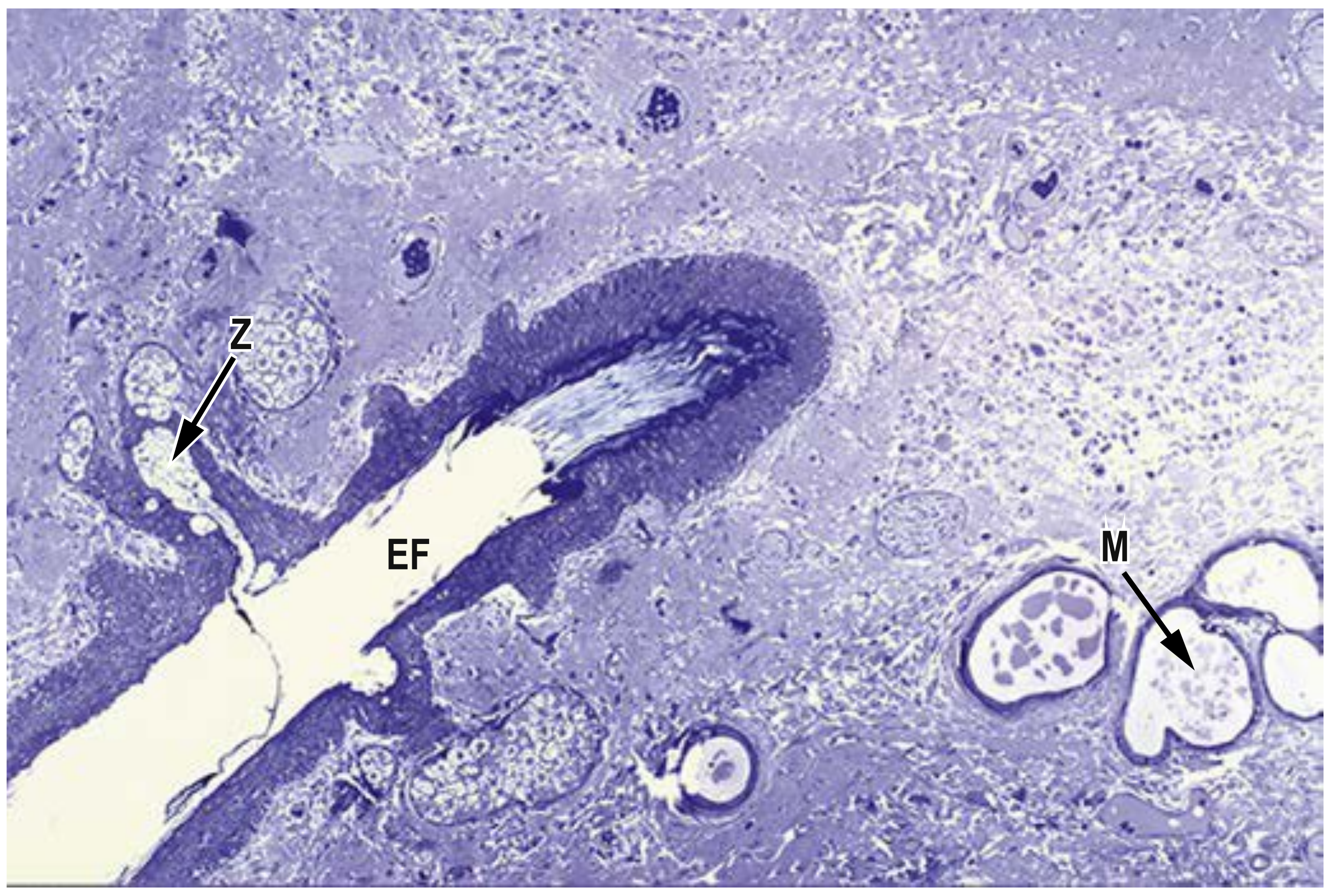

Fig. 2.21 Histological section through the ciliary zone of the eyelid. Glands of Zeis (Z) discharge their contents into an eyelash follicle (EF), which contains the remnants of an eyelash. M = gland of Moll.

Glands of Zeis and Moll. Ciliary glands of Zeis and Moll are found in association with eyelash follicles (Takahashi et al., 2013) (Fig. 2.21). Zeis glands are unilobular sebaceous glands that open directly into the follicle. The function of their oily secretion is to lubricate the lashes to prevent them from drying out and becoming brittle. Glands of Moll are modified sweat glands (apocrine) consisting of an unbranched spiral tubule. The exact function of these glands is unclear, although their secretion is rich in IgA, which suggest a role in the immune defence of the ocular surface (Stoeckelhuber et al., 2003).

Blood and Nerve Supply

Nerves of the Eyelids. The levator palpebrae and orbicularis oculi muscles are innervated by the oculomotor and facial nerves, respectively. The sensory supply of the upper lid derives from branches of the ophthalmic nerve (supraorbital, supratrochlear and lacrimal). The supply to the lower lid comes from branches of the maxillary nerve (zygomatic, infraorbital).

Blood and Lymphatic Supply to the Eyelids. The arterial supply derives from branches of the ophthalmic, lacrimal and infraorbital arteries, which contribute to two palpebral arcades in the upper lid and one in the lower. Branches from these arcades supply the skin, orbicularis, tarsal glands and palpebral conjunctiva. Veins of the eyelids empty into veins of the forehead and temple, and some empty into the ophthalmic vein. Lymphatics drain to the preauricular and submandibular lymph nodes.

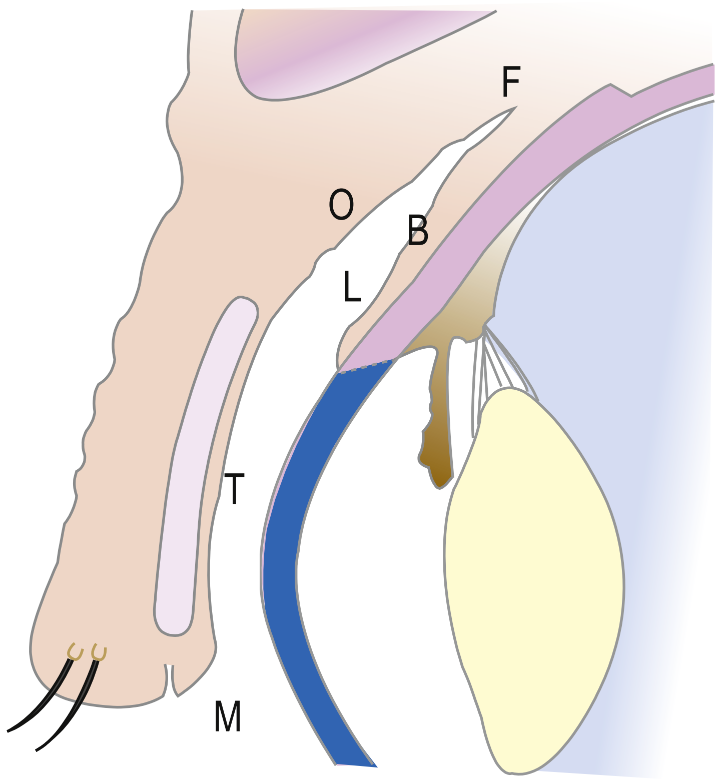

Fig. 2.22 Schematic representation of a mid-sagittal section through the eyelid and conjunctival sac showing the different conjunctival regions. M = marginal; T = tarsal; O = orbital; B = bulbar; L = limbal; F = fornical.

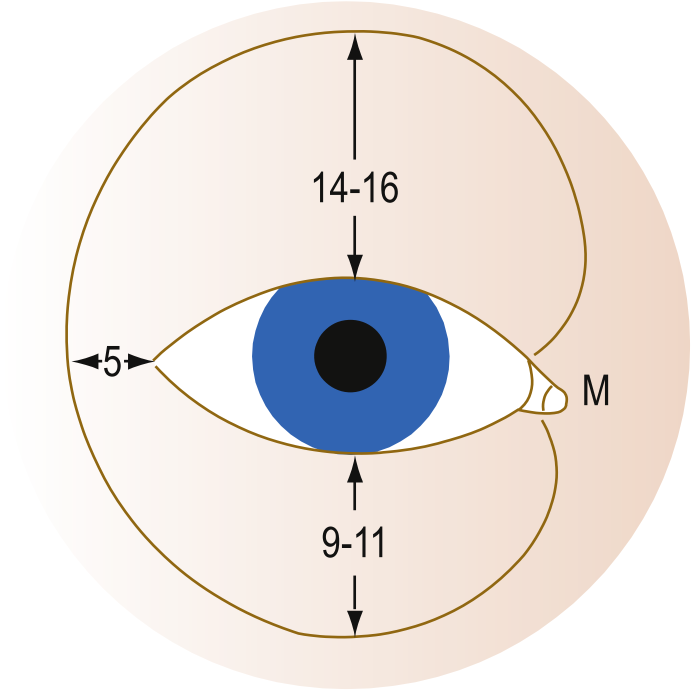

Fig. 2.23 Static dimensions of the conjunctival sac in millimetres. M = medial canthus. (Adapted from Ehlers, N. (1965). On the size of the conjunctival sac. Acta Ophthalmol., 43, 205–210.)

THE CONJUNCTIVA

Gross Anatomy

The conjunctiva is a thin transparent mucous membrane that extends from the eyelid margins anteriorly, providing a lining to the lids, before turning sharply upon itself to form the fornices, from where it is reflected onto the globe, covering the sclera up to its junction with the cornea. It thus forms a sac that opens anteriorly through the palpebral fissure. The conjunctiva is conventionally divided into the following regions: marginal, tarsal, orbital (these three collectively form the palpebral conjunctiva), bulbar and limbal (Fig. 2.22).

The static dimensions of the conjunctival sac in the primary position are illustrated in Fig. 2.23 (Ehlers, 1965). The marginal zone extends from a line immediately posterior to the openings of the tarsal glands and passes around the eyelid margin, from where it continues on the inner surface of the lid as far as the subtarsal fold (a shallow groove that marks the marginal edge of the tarsal plate). The tarsal conjunctiva is highly vascular and is firmly attached to the underlying fibrous connective tissue. From the convex border of the tarsal plate, the orbital zone

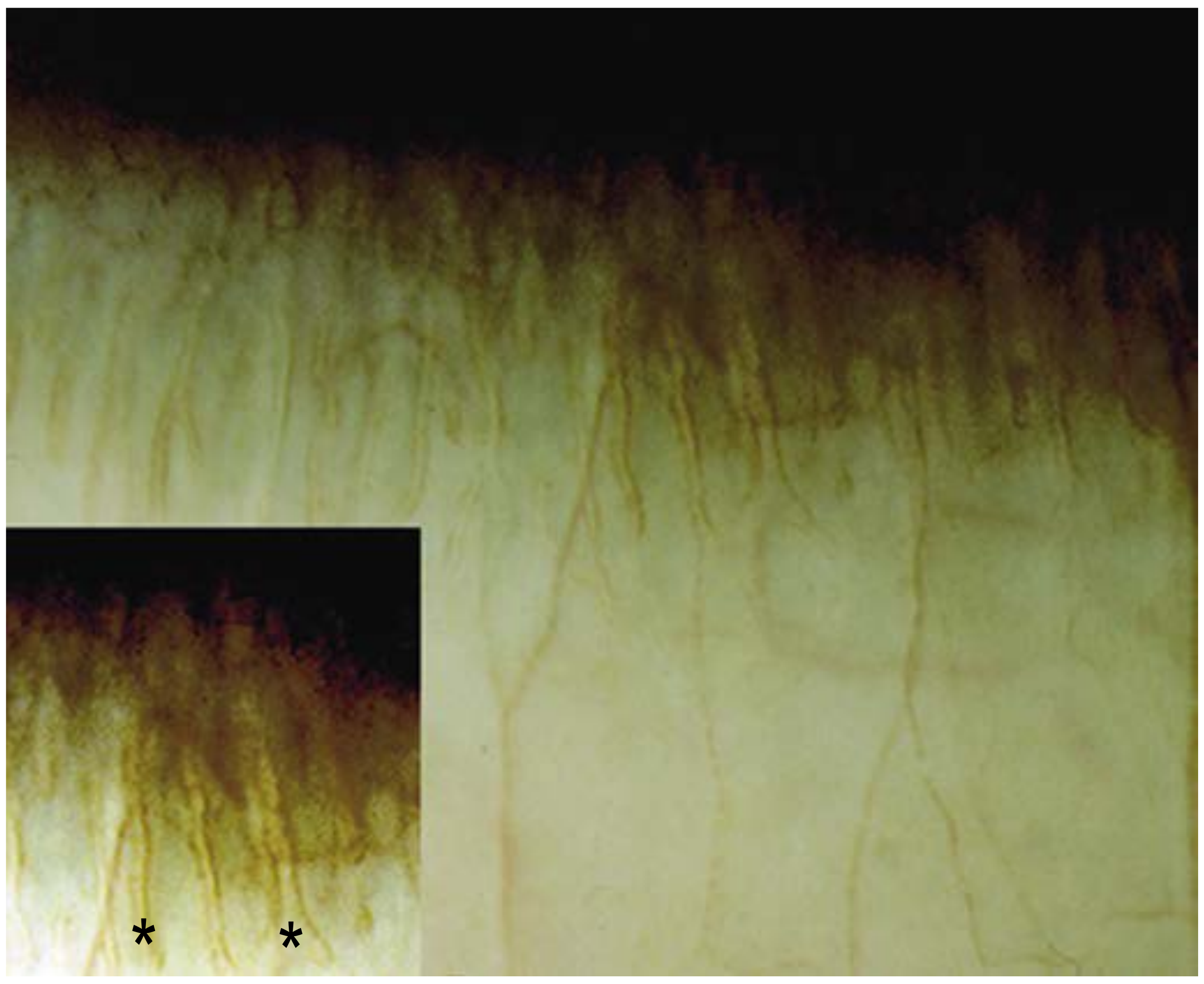

Fig. 2.24 High-power slit-lamp view of the conjunctival palisades of Vogt (asterisks) at the lower limbus.

extends as far as the fornices. Over this region the conjunctiva is more loosely attached to underlying tissues, and so readily folds. Elevations of the conjunctival surface in the form of papillae and lymphoid follicles are commonly observed in this region.

The transparency of the bulbar conjunctiva readily permits the visualization of conjunctival and episcleral blood vessels. Here, the conjunctiva is freely movable owing to its loose attachment to Tenon's capsule (the fascial sheath of the globe). As the bulbar conjunctiva approaches the cornea, its surface becomes smoother and its attachment to the sclera increases. The limbal conjunctiva extends approximately 1–1.5 mm around the cornea. Its junction with the cornea is ill defined, particularly in the vertical meridian, owing to a variable degree of conjunctival / scleral overlap. The limbus has a rich blood supply, and in the majority of individuals a radial array of connective tissue elevations – the palisades of Vogt – can be seen adjacent to the corneal margin (Fig. 2.24). The palisades are most prominent in the vertical meridian, and their visibility is enhanced in pigmented eyes.

Microscopic Anatomy

In histological section, two distinct layers can be resolved: an epithelium containing a variable number of goblet cells, and a vascular stroma that consists of a superficial lymphoid layer and a deep fibrous layer (Fig. 2.25). The appearance of the conjunctiva shows a marked regional variability.

Epithelium. In the marginal zone, the epithelium is stratified and squamous with relatively few goblet cells, although this has recently been disputed following the description of intracellular crypts lined with goblet cells lying deep within the epithelium in the region of the so-called 'lid wiper' region (Knop et al., 2012). It has been suggested that a subpopulation of epithelial cells that lie close to the mucocutaneous junction may be acting as stem cells for the palpebral conjunctiva (Wirtschafter et al., 1999). Approaching the tarsus, the epithelium thins to 2–3 layers of cuboidal cells with scattered goblet cells. The epithelium of the orbital zone is slightly thicker (2–4 cells) with more numerous goblet cells. The number of goblet cells declines over the bulbar conjunctiva and at the limbus the epithelium is again stratified squamous, and goblet cells are absent. The limbus contains a unique array of connective tissue ridges (the palisades of Vogt), which project into the overlying epithelium (Fig. 2.26). Clinical and experimental evidence suggests that the palisades are the repositories of stem cells and therefore act as the regenerative organ of the corneal epithelium (Dua and Azuara-Blanco, 2000). The conjunctival epithelium additionally contains several non-native cell types, including dendritic cells, melanocytes and lymphocytes.

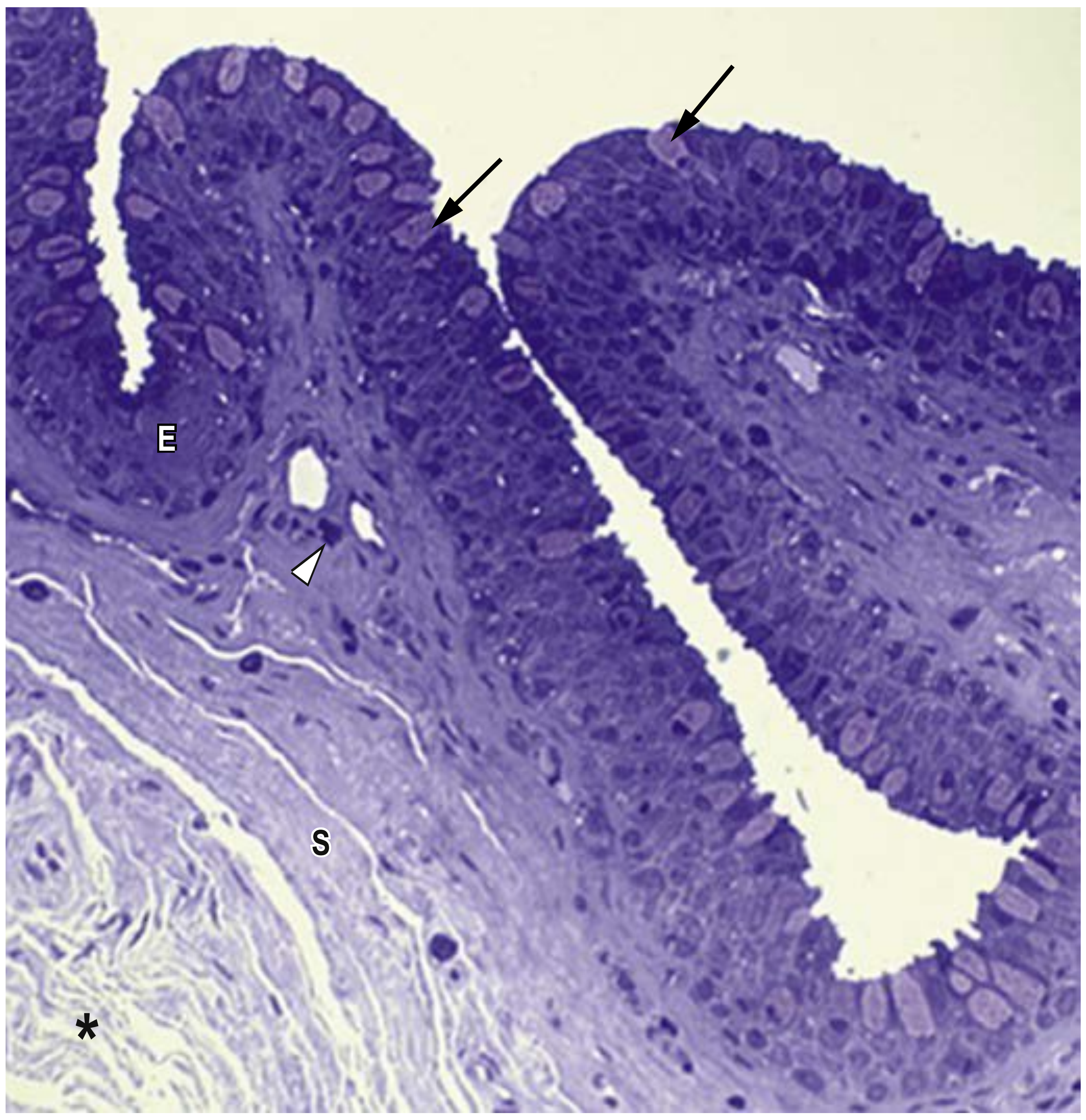

Fig. 2.25 Histological section through the bulbar conjunctiva. E = epithelium; S = stroma. Goblet cells can be seen in the epithelium (arrows). The stroma can be resolved into an adenoid layer (arrowhead) and a deep fibrous layer (asterisk).

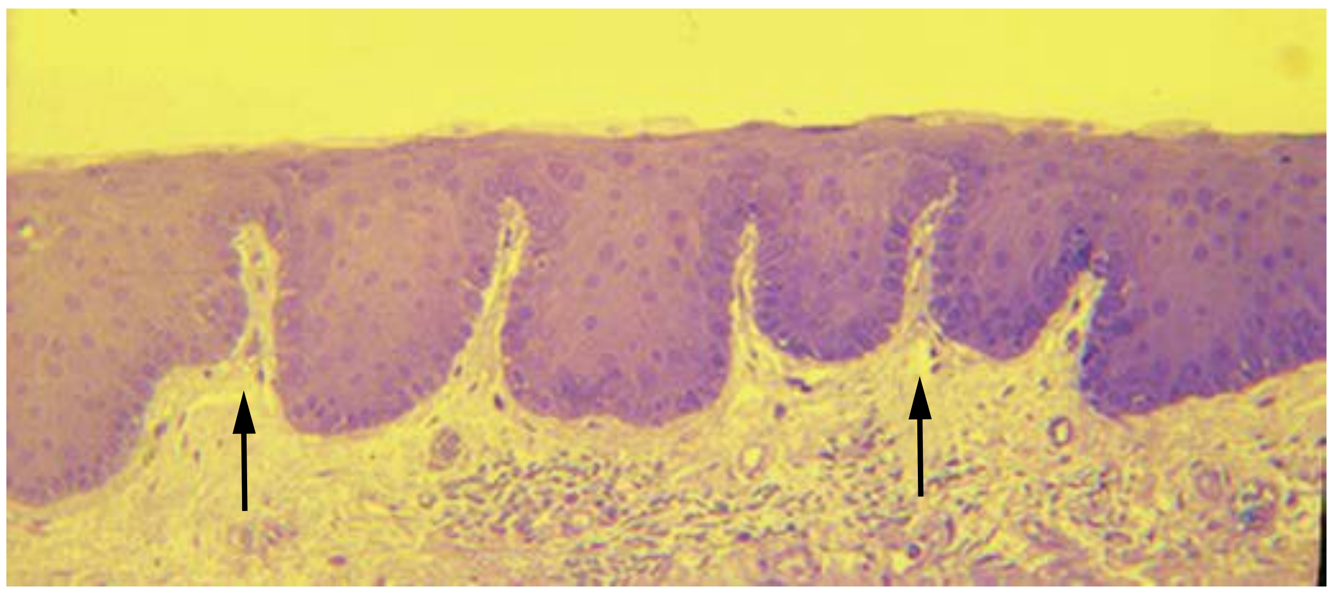

Fig. 2.26 Histological section through the palisade region. Connective tissue ridges can be seen projecting into the overlying epithelium (arrows).

Goblet and Other Secretory Cells. Goblet cells provide the mucous component of the tear film. They arise in the basal cell layers and migrate to the surface, there becoming fully differentiated. Mature goblet cells are larger than the surrounding epithelial cells and contain a peripherally placed nucleus. The cytoplasm is packed with membrane-bound secretory granules that discharge from the apical surface in an apocrine manner. The number of goblet cells shows a marked regional variation in density (Kessing, 1968) (Fig. 2.27), and these cells are occasionally seen lining intraepithelial crypts (of Henle).

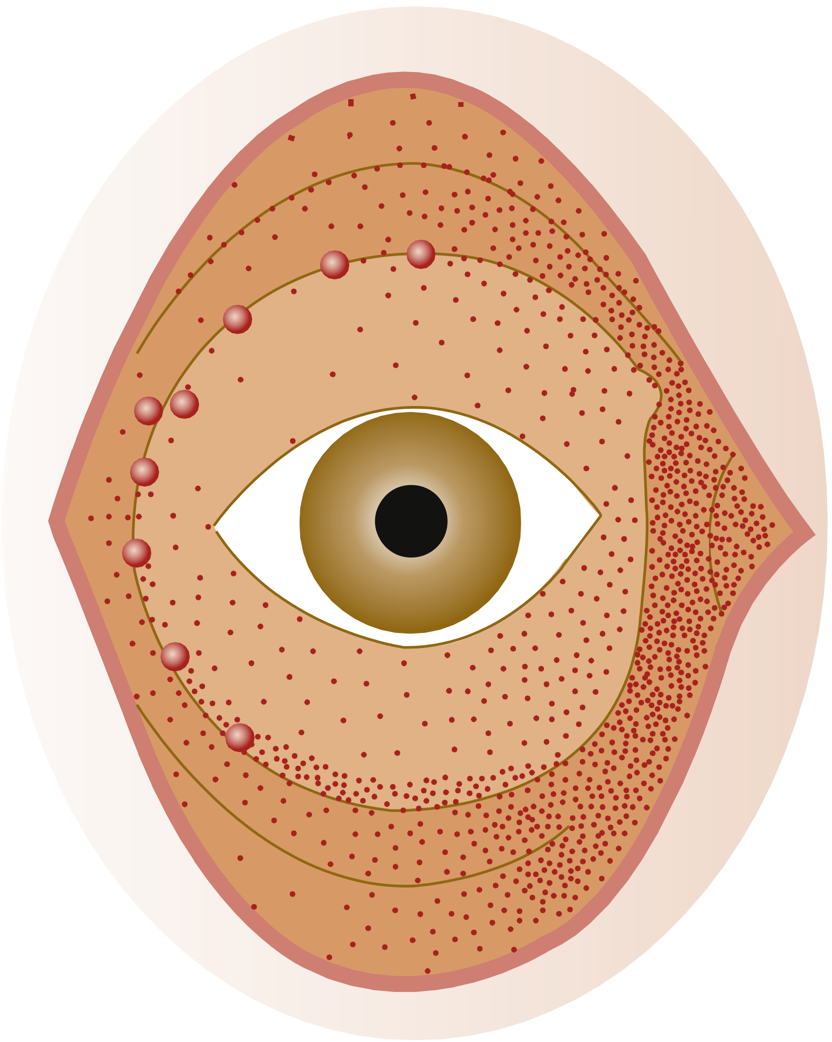

Fig. 2.27 Diagram showing the regional variation in goblet cell density. Goblet cell density is greatest over the caruncle, plica semilunaris and inferior nasal palpebral conjunctiva. (Adapted from Bron, A. J., Tripathi, R. C. & Tripathi, B. (1997). Wolff's Anatomy of the Eye and Orbit (8th ed.). London: Chapman and Hall. Reproduced from Bron, 1997.)

The apices of many surface epithelial cells of the conjunctiva contain numerous carbohydrate-containing secretory vesicles, which are seen to migrate to the cell surface where they fuse with the plasma membrane (Dilly, 1985). It is likely that this represents a mechanism for recycling the cell surface glycocalyx rather than a secondary source of secretory mucin.

Conjunctival Stroma. The conjunctival stroma (substantia propria) is variable in thickness. It can be resolved into two distinct layers: a superficial adenoid layer and a deeper fibrous layer (see Fig. 2.25). The adenoid layer contains numerous lymphocytes with local accumulations in the form of lymphoid follicles (Fig. 2.28). Follicles represent aggregates of predominantly B cells, which form part of the so-called conjunctiva-associated lymphoid tissue (Knop and Knop, 2005). The adenoid layer also contains a large number of mast cells, which play a major role in ocular allergy (McGill et al., 1998). The deep fibrous layer is generally thicker than the adenoid layer and contains the majority of conjunctival blood vessels and nerves.

Innervation and Blood Supply

Nerves. The conjunctiva receives nerves from sensory, sympathetic and parasympathetic sources. Sensory nerves, which are trigeminal in origin, reach the conjunctiva via branches of the ophthalmic nerve. The principal function of these fibres is to equip the conjunctiva with the ability to detect a variety of sensations – for example, touch, pain, warmth and cold. Sensory nerve terminals include both free (unspecialized) nerve endings and the more complex corpuscular endings (classically referred to as Krause end bulbs) (Lawrenson and Ruskell, 1991). Conjunctival blood vessels receive a dual autonomic innervation. Parasympathetic fibres issuing from the pterygopalatine ganglion and sympathetic fibres from the superior cervical ganglion are responsible for vasodilation and vasoconstriction, respectively.

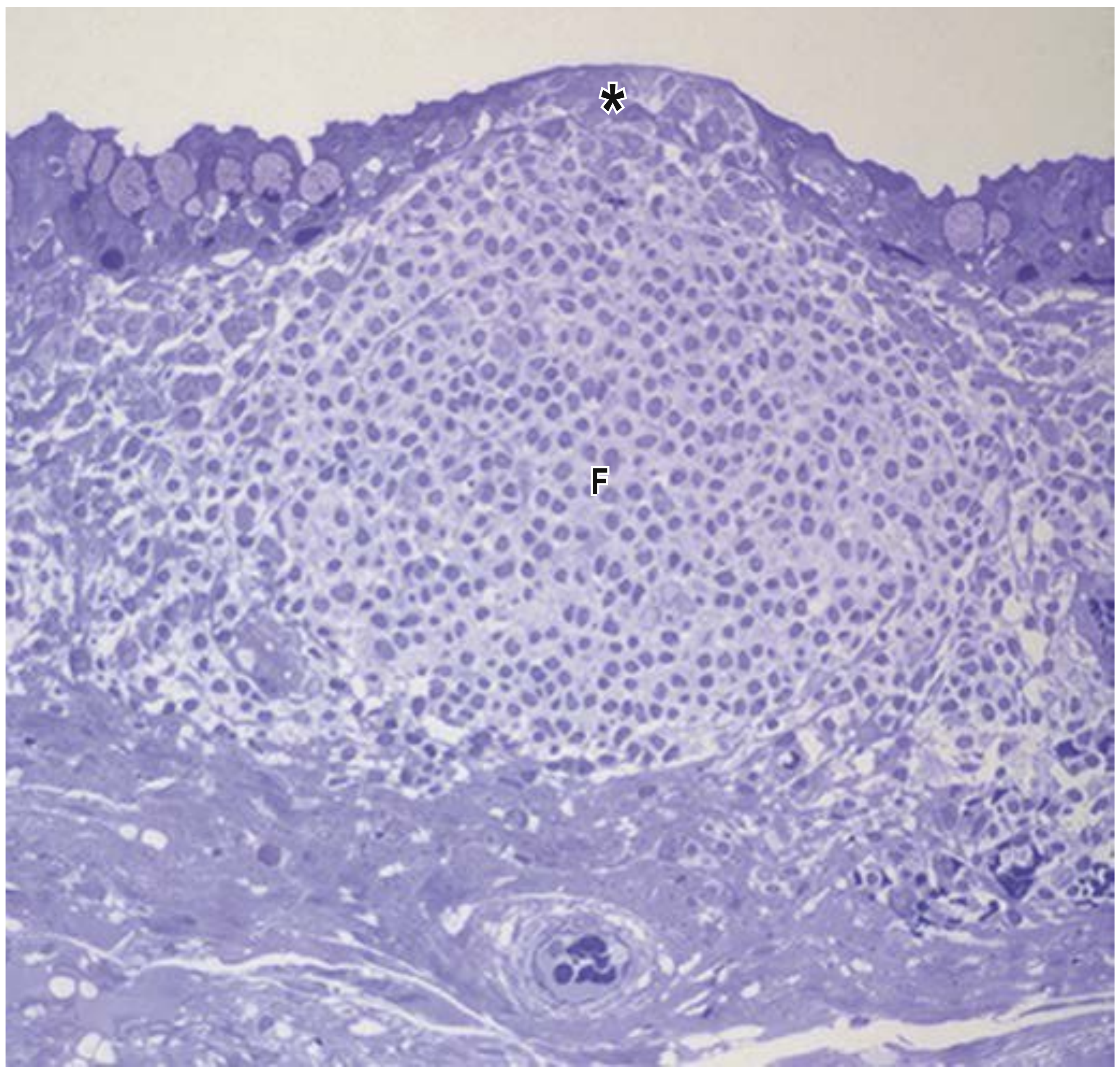

Fig. 2.28 Histological section through a lymphoid follicle (F). Note the modification of the overlying epithelium (asterisk).

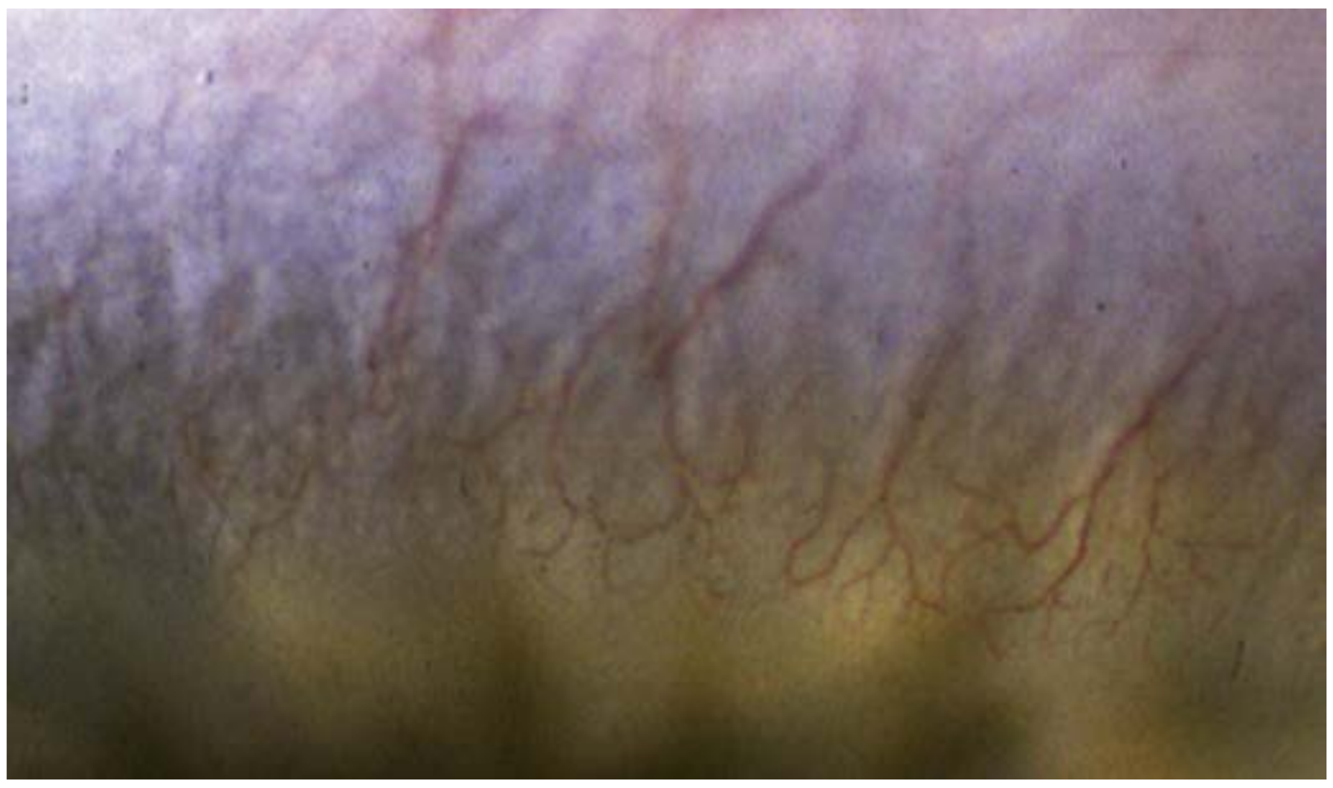

Fig. 2.29 High-power slit-lamp photograph showing the limbal vascular arcades. (Courtesy of Eric Papas.)

Blood Vessels and Lymphatics. The arterial supply derives from two sources: palpebral branches of the nasal and lacrimal arteries, and anterior ciliary arteries.

Palpebral vessels serve two vascular arcades within the eyelid. The inferior (marginal) arcade sends branches through the tarsal plate to the eyelid margin and tarsal conjunctiva. The superior (palpebral) arcade supplies the tarsal, orbital, fornix and bulbar conjunctiva. The limbal zone, in contrast, is served by anterior ciliary arteries. The anterior ciliary arteries travel along the tendons of the rectus muscles and give off branches at episcleral level prior to dipping down into the sclera to link with the major iridic circle. Episcleral branches pass forward and loop back a few millimetres short of the cornea to become conjunctival vessels. Forward extensions of these vessels form the limbal arcades (limbal loops), which are a complex network of fine capillaries (Fig. 2.29). Conjunctival veins are more numerous than arteries. They can be readily differentiated from arteries owing to their larger calibre, darker colour and more tortuous path.

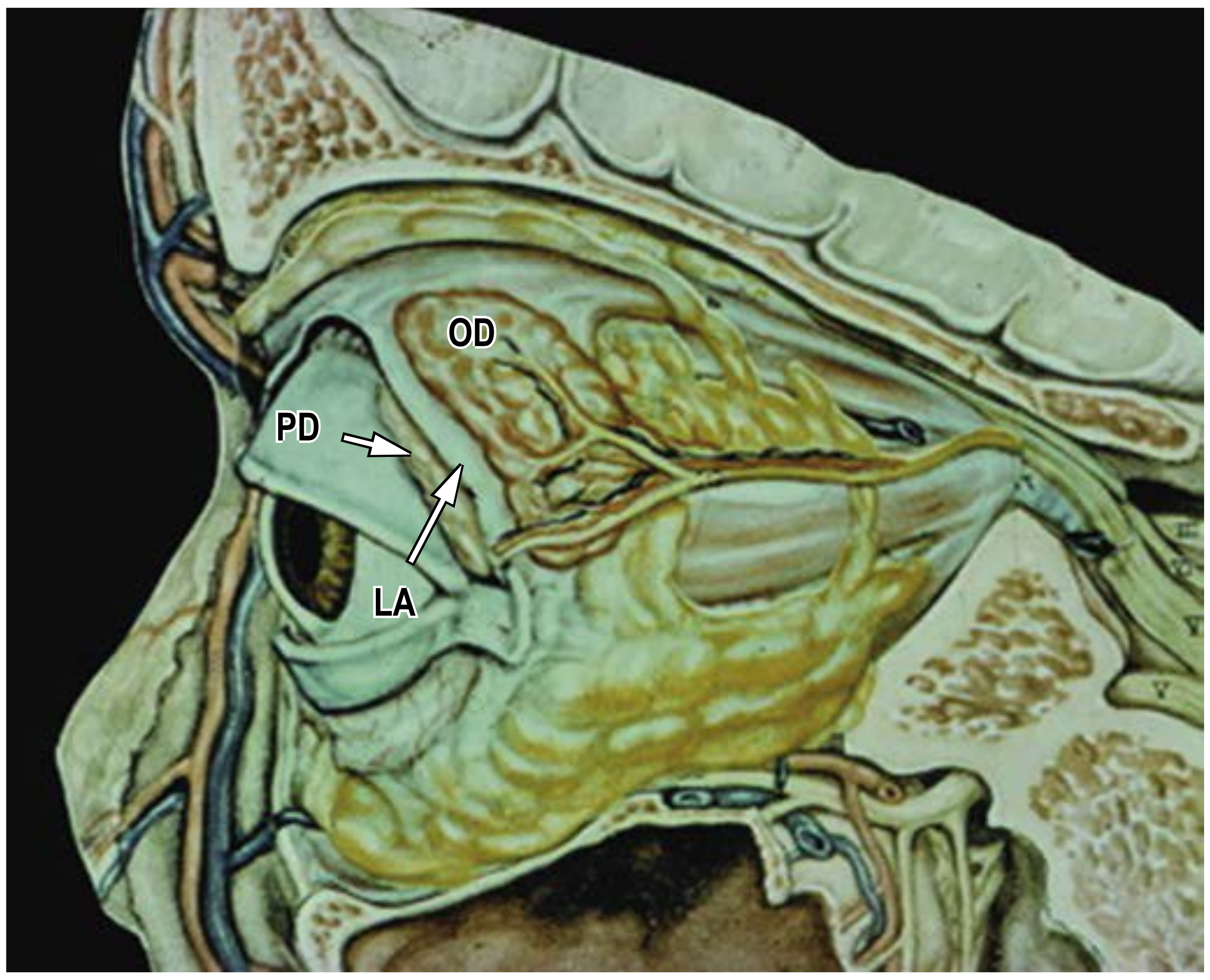

Fig. 2.30 Lateral view of the orbit showing the position of the lacrimal gland. The levator aponeurosis (LA) partially divides the gland into an orbital (OD) and palpebral (PD) division. (Adapted from Kronfeld, P. C., McHugh, S. L. & Polyak, S. L. (1943). The Human Eye in Anatomical Transparencies. Rochester, NY: Bausch & Lomb.)

Functional Considerations

The conjunctiva contributes the mucin component of the preocular tear film and plays an important role in the defence of the ocular surface against microbial infection. Mucins are a family of high-molecular-weight glycoproteins that include membrane-bound and secretory varieties (Corfield et al., 1997; Gipson and Inatomi, 1997; Hodges and Dartt, 2013). Goblet cells are the primary source of secretory mucin, whilst surface epithelial cells of both the conjunctiva and cornea possess mucin-like molecules within their glycocalyx. The conjunctiva also forms part of a common mucosal defence system, which is an important component of the defence of the human body against microorganisms (McClellan, 1997; Knop and Knop, 2005). The conjunctiva possesses the immunological capacity for antigen processing, and cell-mediated and humoral immunity. Humoral immunity is provided by specific antibodies (particularly immunoglobulin A [IgA]) produced by transformed B cells (plasma cells) in the stroma. T lymphocytes form the basis of cell-mediated immunity.

LACRIMAL SYSTEM

The lacrimal apparatus provides for the production and maintenance of the preocular tear film. The normal function of this system is essential for the integrity of the ocular surface and the provision of a smooth refractive surface. The lacrimal apparatus comprises a secretory system that includes the main and accessory lacrimal glands, and a drainage system that consists of the paired puncta and canaliculi, the lacrimal sac and the nasolacrimal duct.

Lacrimal Gland

Gross Anatomy. The main lacrimal gland is the key provider of the aqueous component of the tears. The gland is located in a shallow depression of the frontal bone behind the superolateral orbital rim (Fig. 2.30). It is partially split by the aponeurosis of the levator palpebrae into an upper larger orbital lobe and a lower palpebral lobe, which can often be visualized through the conjunctiva upon lid eversion (Bron, 1986). The gland is pinkish in colour, with a lobulated surface. Between 6 and 12 ducts leave the gland through the palpebral lobe and discharge into the conjunctival sac at the upper lateral fornix.

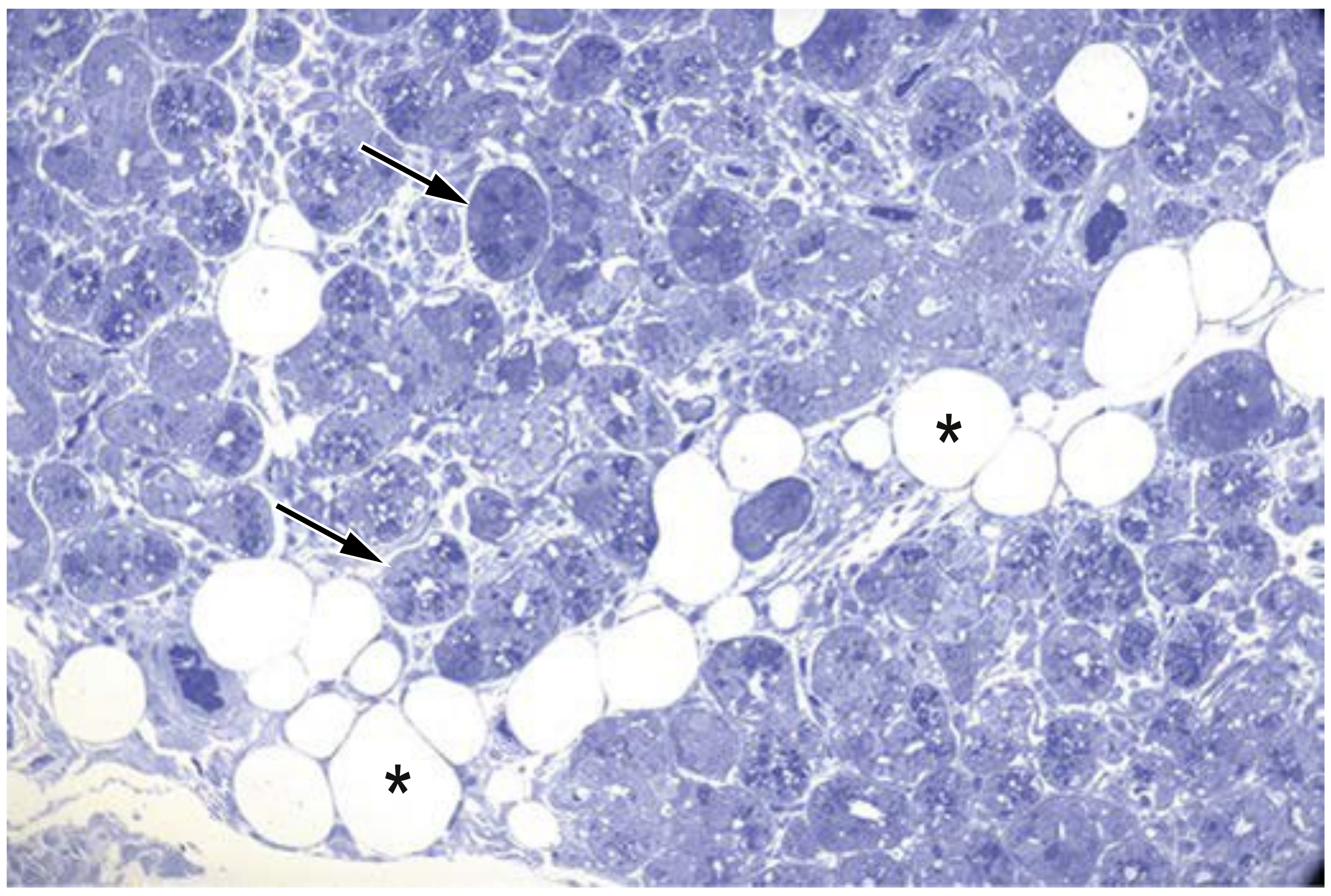

Fig. 2.31 Low-power light micrograph of the lacrimal gland. Acini are arrowed. Adipose connective tissue (asterisks) extends across the gland.

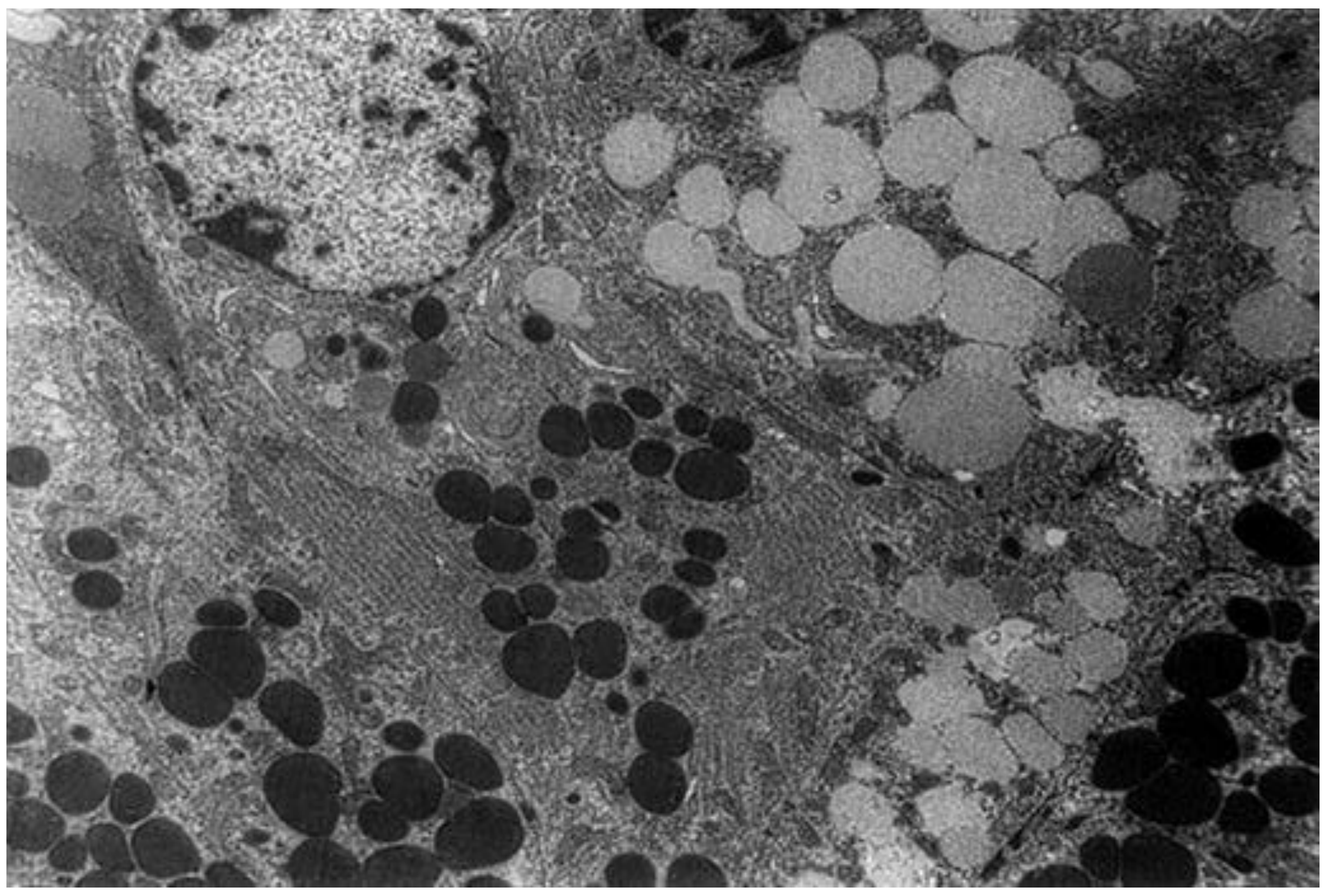

Fig. 2.32 Electron micrograph of part of a lacrimal acinus showing light and dark secretory cells.

Microscopic Anatomy. The lacrimal gland is tubuloacinar in form (Fig. 2.31). Its secretory units (acini) contain secretory cells surrounded by myoepithelial cells (Ruskell, 1975). Acinar secretory cells show extensive folding of their plasma membrane and apical microvilli. Adjacent cells are linked by tight junctions that restrict diffusion between cells. The most prominent feature of these cells is the presence of abundant secretory granules. Two principal secretory cell subtypes have been identified on the basis of their granule content (Fig. 2.32). The majority of cells contain dark granules (dark cells), with a smaller number of cells containing light granules (light cells). The functional significance of this heterogeneity is uncertain at present. Ducts consist of a single layer of cuboidal cells that lack secretory granules. Myoepithelial cells are dendritic cells that are closely associated with the perimeter of acini and ducts. It is likely that these contractile cells play a role in the expulsion of tears from the gland. The interstices of the gland contain numerous blood vessels and nerves. A large population of immune cells (particularly IgA-secreting plasma cells) are also found between acini.

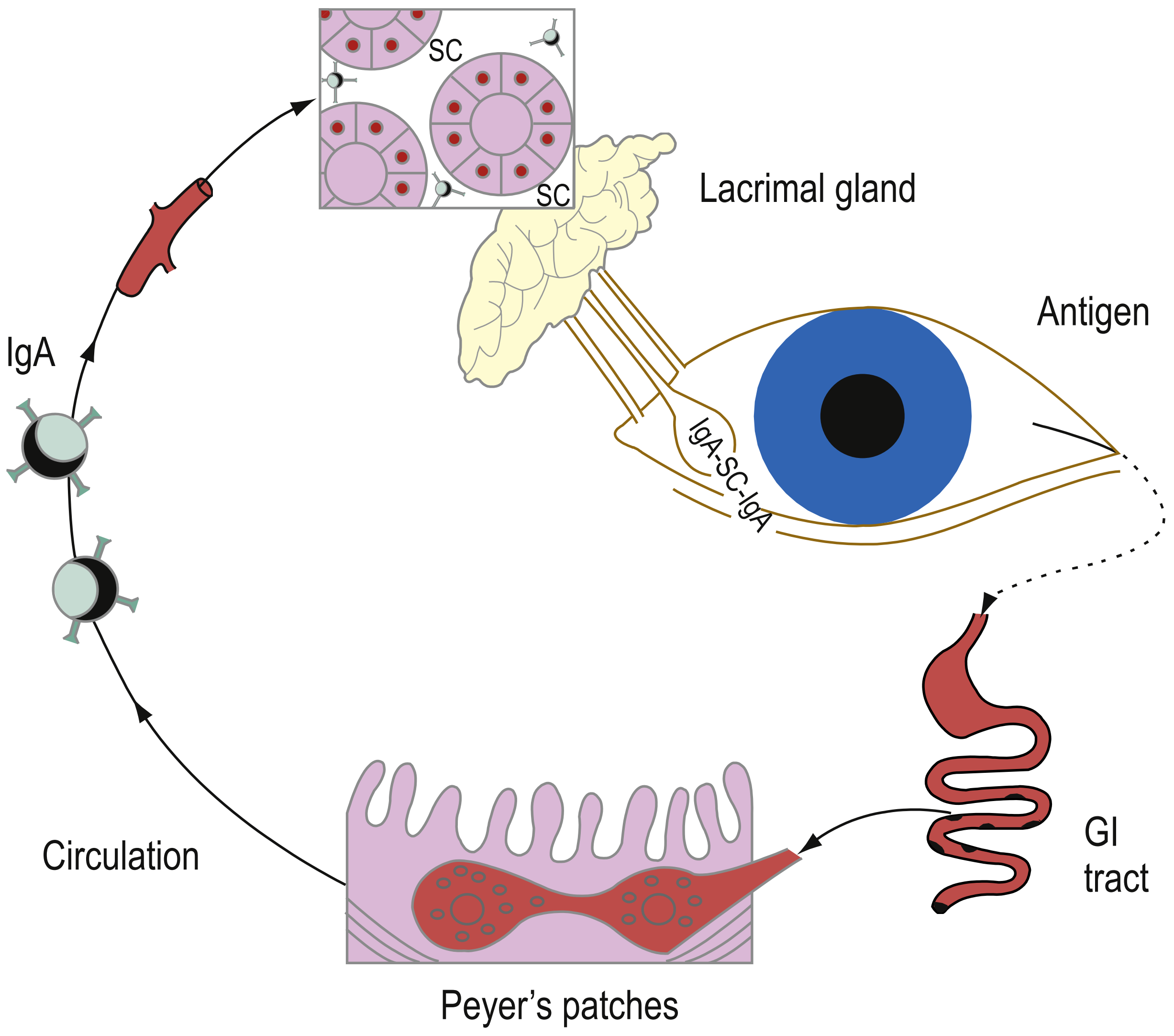

Fig. 2.33 Diagram showing the role of the gastrointestinal tract generating specific immunoglobulin A (IgA) in the lacrimal gland. Antigens which challenge the ocular surface ultimately drain to the gastrointestinal (GI) tract where they stimulate B cells in Peyer's patches (gut-associated lymphoid tissue). Sensitized B cells then pass to the lacrimal gland via the circulation. SC = secretory component. (Adapted from Allansmith, M. R. (1992). The Eye and Immunology. Maryland Heights, MO: Mosby. Copyright Elsevier 2002.)

Blood and Nerve Supply. The arterial supply to the lacrimal gland is provided by the lacrimal artery, which enters the posterior border of the gland. Venous drainage occurs via the lacrimal vein. A rich autonomic innervation includes secretomotor (parasympathetic) fibres that issue from the pterygopalatine ganglion and sympathetic (vasomotor) fibres from the carotid plexus. The lacrimal nerve traverses the gland to provide a sensory innervation to the conjunctiva and lateral aspect of the eyelid.

Accessory Lacrimal Glands. Numerous small accessory lacrimal glands, which include the eponymous glands of Wolfring and Krause, are found within the conjunctival stroma. They have a particular predilection for the upper fornix and above the tarsal plate, and, on the basis of proportion of total lacrimal tissue, it has been estimated that they contribute 5–10% of aqueous tear volume. Structurally, they have a similar appearance to the lacrimal gland proper. However, true acini are absent and glands consist of elongated tubules that connect with ducts opening onto the conjunctival surface (Seifert et al., 1993).

Functional Considerations. In addition to its role as the principal provider of the aqueous phase of the tear film, the lacrimal gland is also a major component of the ocular sensory immune system, which acts as the first line of defence against microbial infection (Sullivan and Sato, 1994). The secretory immune system is mediated through secretory IgA. The lacrimal gland is the main source of tear IgA and the gland contains a large number of IgA-producing plasma cells. The mechanism by which an antigenic challenge of the ocular surface induces a lacrimal antibody response is not fully understood. However, as the administration of an antigen by a gastrointestinal route raises specific IgA levels in tears, one suggested mechanism is that ocular antigens – after drainage through the nasolacrimal duct – stimulate B cells in gut Peyer's patches. These sensitized B cells then populate the lacrimal gland where they transform into plasma cells (Fig. 2.33).

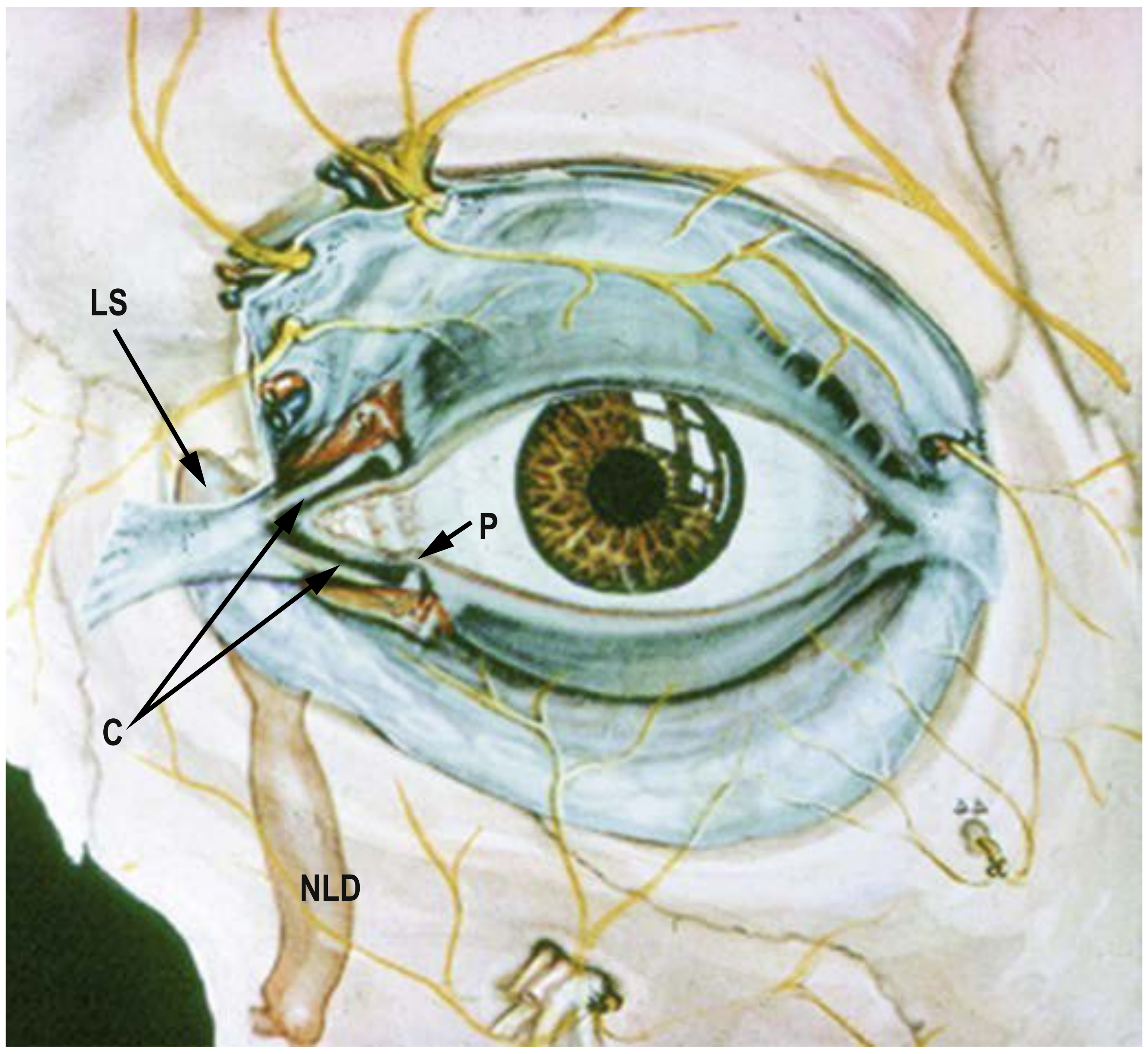

Fig. 2.34 Illustration of the lacrimal drainage system. C = canaliculi; LS = lacrimal sac; P = punctum; NLD = nasolacrimal duct. (Adapted from Kronfeld, P. C., McHugh, S. L. & Polyak, S. L. (1943). The Human Eye in Anatomical Transparencies. Rochester, NY: Bausch & Lomb.)

It has been demonstrated that the lacrimal gland also secretes into the tears growth factors that are important for the maintenance of the ocular surface and epithelial wound healing (Pflugfelder, 1998). Prominent amongst these growth factors are epidermal growth factor and transforming growth factor beta.

Lacrimal Drainage System

Tears collect at the medial canthal angle, where they drain into the puncta of the upper and lower lids. Each punctum is a small oval opening approximately 0.3 mm in diameter that is located at the summit of an elevated papilla. From each punctum the canaliculus passes first vertically for about 2 mm and then turns sharply to run medially for about 8 mm (Fig. 2.34). At the angle, a slight dilation, the ampulla, can be seen. The canaliculi converge towards the lacrimal sac, usually forming a common canaliculus before entry. The lacrimal sac occupies a fossa formed by the maxillary and lacrimal bones. It measures 1.5–2.5 mm in diameter and approximately 12–15 mm in vertical length. From the lacrimal sac tears drain into the nasolacrimal duct, which extends for about 15 mm, passing through a bony canal in the maxillary bone, to an opening in the nose beneath the inferior nasal turbinate. A fold of mucosa is often observed at the termination of the duct: this has been termed 'the valve of Hasner', although there is no strong evidence that it functions as a valve.

The process of tear drainage is an active process mediated by the contraction of the orbicularis during blinking (Doane, 1981). Tears enter the canaliculi principally by capillary action. During the early part of the blink the puncta are occluded as the orbicularis further contracts. The canaliculi and lacrimal sac are also compressed, forcing fluid into the nose. An alternative hypothesis has been proposed whereby orbicularis contraction dilates the sac, creating a negative pressure, which draws in the tears from the canaliculi (Jones, 1961). An investigation by Paulsen et al. (2000) described a vascular plexus embedded in the wall of the lacrimal sac and duct that may influence tear outflow. It is postulated that opening and closing of the lumen of

TABLE 2.2 Physical Properties of the Preocular Tear Film

Parameter	Value
Osmolarity	302 (±6.3) mOsm/l
pH	7.45
Thickness	3 µl
Volume	7.0 (±0.2) µl
Rate of production	
Unstimulated	1–2 µl/min
Stimulated	>100 µl/min
Refractive index	1.336

the lacrimal passages can be achieved by regulating blood flow within this plexus.

The Preocular Tear Film

FUNCTION AND PROPERTIES OF THE PREOCULAR TEAR FILM

The tear film is a complex fluid that covers the exposed parts of the ocular surface framed by the eyelid margins. The physical characteristics of this fluid are summarized in Table 2.2. Classically, the tear film has been regarded as a trilaminar structure with a superficial lipid layer secreted by the meibomian glands, which overlies an aqueous phase derived from the main and accessory lacrimal glands, and an inner mucinous layer consisting of membrane-spanning mucins of the ocular surface epithelium and secretory mucins produced mainly by conjunctival goblet cells. The tear film performs several important functions, which can be broadly classified as optical, metabolic support, protective and lubrication.

By smoothing out irregularities of the corneal epithelium, the tear film creates an even surface of good optical quality that is reformed with each blink. The air–tear interface forms the principal refractive surface of the optical system of the eye and provides two-thirds (43 D) of its total refractive power. As the cornea is avascular it is dependent on the tear film for its oxygen provision. When the eye is open the tear film is in a state of equilibrium with the oxygen in the atmosphere, and gaseous exchange takes place across the tear interface. The constant turnover of the tear film also provides a mechanism for the removal of metabolic waste products.

Tears play a major role in the defence of the eye against microbial colonization. The washing action of the tear fluid reduces the likelihood of microbial adhesion to the ocular surface. Moreover, the tears contain a host of protective antimicrobial proteins. The tear film acts as a lubricant, smoothing the passage of the lids over the corneal surface and preventing the transmission of damaging shearing forces. To facilitate this, tear fluid displays non-Newtonian behaviour with respect to shear (Tiffany, 1991). Newtonian fluids maintain a constant viscosity with increasing shear rates. By contrast, tear fluid has a relatively high viscosity between blinks to aid stability, and with increasing shear rates during the blink process the viscosity falls dramatically, thereby easing the movement of the lids over the ocular surface.

Tear Production

Jones (1966) first used the terms 'basic (basal)' and 'reflex' to describe tear flow. He proposed that the accessory lacrimal glands were the basic (minimal flow) secretors, and that reflex secretion (i.e. in response to strong physical or emotional stimulation) is mediated by the main lacrimal gland. However, Jordan and Baum (1980) questioned the concept of basic and reflex secretion, and suggested that it is more accurate to think of tear output as a continuum, whereby the rate of production is proportional to the degree of sensory or emotive stimulation (Dartt, 2009). This concept would also mean that a functional distinction between main and accessory lacrimal glands, in terms of basal and reflex tear production, is unnecessary. Rather, it is more likely that tear flow is the combination of contributions from both glands, although the output from the accessory glands alone is sufficient to maintain a stable tear layer (Maitchouk et al., 2000).

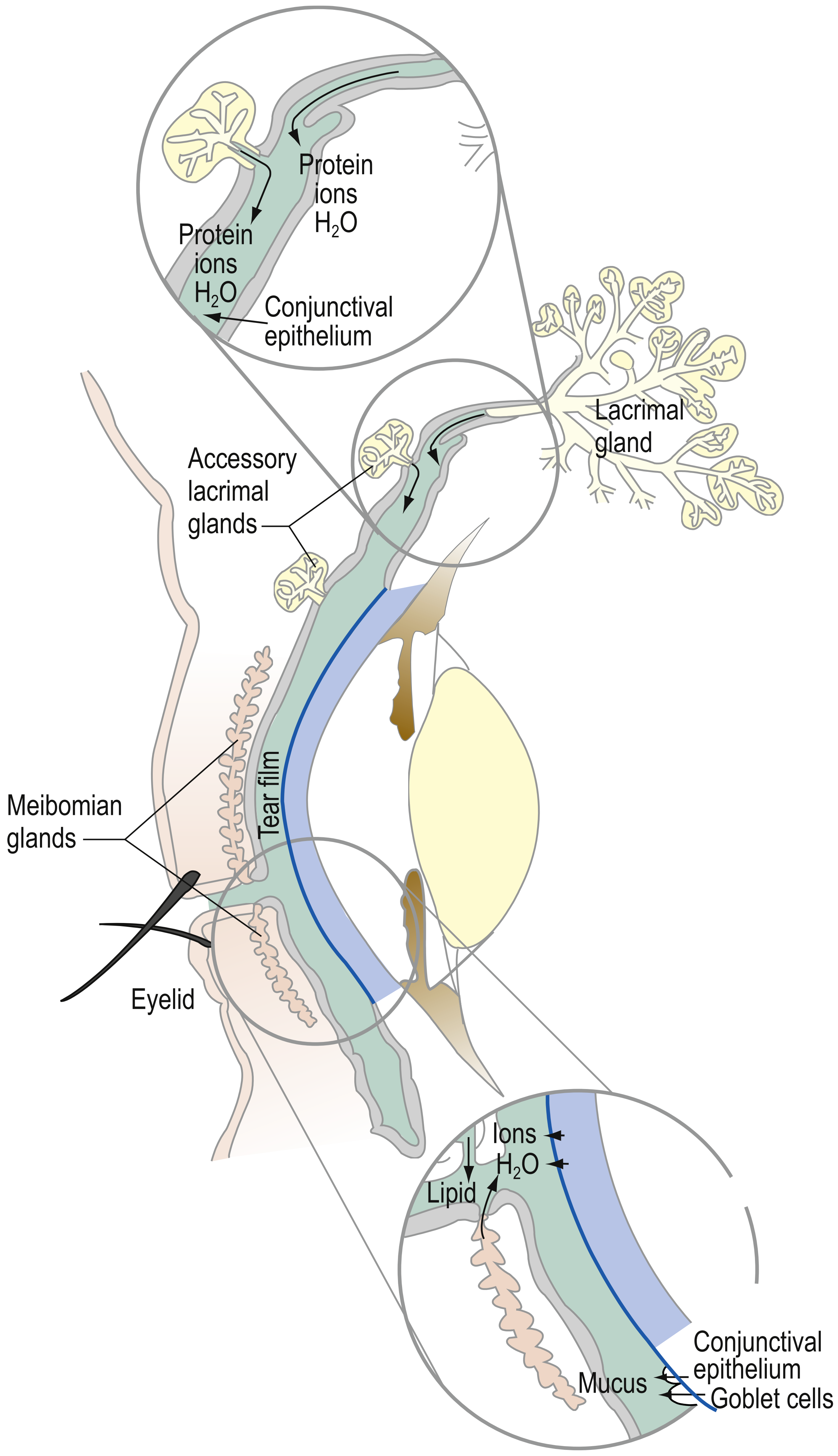

Fig. 2.35 Schematic representation of the orbital glands, which contribute the various components of the preocular tear film. (Adapted from Dartt, D. A. (1992). Physiology of tear production. In M. A. Lemp & R. Marquardt (eds) The Dry Eye: A Comprehensive Guide. Berlin: Springer-Verlag.)

SOURCES AND COMPOSITION

Tears are composed of a complex secretion that combines the products of several glands (Fig. 2.35). Although the precise composition of tear fluid varies with collection method, flow rate and time of day, it can be considered as a watery secretion containing electrolytes and proteins, with lesser amounts of lipid and mucin.

TABLE 2.3 Biochemical Composition of the Preocular Tear Film

Component	Concentration
ELECTROLYTES*	
Na^+	135 mEq/l
Cl^-	131 mEq/l
K^+	36 mEq/l
HCO_3^-	26 mEq/l
Ca^{2+}	0.46 mEq/l
Mg^{2+}	0.36 mEq/l
MAJOR PROTEINS*	
Lysozyme	2.07 g/l
Secretory IgA	3.69 g/l
Lactoferrin	1.65 g/l
Lipocalin	1.55 g/l
Albumin	0.04 g/l
IgG	0.004 g/l
LIPIDS†	
Wax esters	41%
Cholesteryl esters	27.3%
Polar lipids	14.8%
Hydrocarbons	7.5%
Diesters	7.7%
Triacylglycerides	3.7%
Fatty acids	2.0%
Free sterols	1.6%
MUCIN‡	
MUC1	nd
MUC5AC	nd
MUC4	nd
MUC16	nd

(Data adapted from Tiffany, 1997.)
Sources:
*Main and accessory lacrimal glands.
†Meibomian glands.
‡Epithelial cells/goblet cells.
nd = not determined.

Electrolytes

Human tears contain approximately the same range of electrolytes as found in plasma (Tiffany, 1997). Table 2.3 gives typical values for the ionic composition of human tears. However, as the electrolyte content of tears varies with flow rate, there is significant variation in measured values. During the process of secretion by the lacrimal gland, there is a process of active electrolyte transport that is coupled to the passive movement of water by an osmotic process. Acinar-derived fluid is essentially an isotonic ultrafiltrate of plasma. Its composition is altered as it passes along the ductal system, where further chloride and potassium ions are secreted. A variety of ion transport proteins have been identified in acinar cells, including sodium–potassium ATPase and potassium and chloride channels.

Proteins

Tear proteins are thought to originate from three main sources: the lacrimal gland, ocular surface epithelia and conjunctival blood vessels. The major lacrimal proteins include secretory IgA, lysozyme, lactoferrin and lipocalin (formerly known as tear-specific prealbumin) (see Table 2.3). IgA, which is the major immunoglobulin in tears, is secreted as a dimer by plasma cells in the interstices between lacrimal acini. It then binds to a receptor on the basolateral aspect of acinar cells, and is transcytosed across the cell and secreted into tear fluid. IgA is a constitutively secreted lacrimal protein whose rate of secretion is independent of flow rate. During sleep, the levels of IgA increase as secretory IgA production continues and as acinar secretion declines (Sack et al., 1992). IgA plays an important role in the defence of the ocular surface against microbial infection by preventing bacterial and viral adhesion, and inactivating bacterial toxins. Other immunoglobulins (e.g. IgG and IgM) are present in tears at much lower levels.

Lysozyme, lactoferrin and lipocalin, in contrast, originate from acinar cells and their rate of secretion roughly matches flow rate. Lysozyme is a well-known bacteriolytic protein that has the ability to lyse the cell wall of several Gram-positive bacteria. Lactoferrin serves an important bacteriostatic function by binding iron and making it unavailable for bacterial metabolism. It also acts as a free radical scavenger, thereby reducing free-radical-mediated cell damage (Tiffany, 1997). Lipocalins are a family of lipid-binding proteins with an affinity for a broad array of lipids, including fatty acids, phospholipids and cholesterol. It has been suggested that tear lipocalins act as scavengers for a wide range of meibomian lipids, which could spill onto the corneal surface and perturb its wettability (Glasgow et al., 2000). Furthermore, lipocalin may promote lipid solubility at the aqueous–lipid interface to facilitate the formation of a thin layer of lipid on the surface of the tear film.

Mucins

Mucins are a family of high-molecular-weight glycoproteins, of which sugars contribute up to 85% of their dry weight. Structurally, they consist of a polypeptide backbone to which chains of sugar molecules attach via O-linkages to the amino acids serine and threonine. Mucins are a heterogeneous group of molecules that can be subdivided into secretory and integrated-membrane varieties (Corfield et al., 1997; Hodges and Dartt, 2013). So far, modern molecular biology techniques have identified up to 20 mucin (MUC) genes, although only four of these (MUC1, MUC5AC, MUC4 and MUC16) are expressed on the human ocular surface (Gipson and Inatomi, 1997; McKenzie et al., 2000; Pflugfelder et al., 2000; Mantelli and Argüesco, 2008). The epithelia of the cornea and conjunctiva express the transmembrane mucins MUC1, and to a lesser extent MUC4 and MUC16, which attach to apical microvilli where they form a hydrophilic base to facilitate the spreading of the goblet-cell-derived mucin MUC5AC. Mucins play a major role in stabilizing and spreading the tear film and provide protection against desiccation and microbial invasion (Gipson and Inatomi, 1997; Hodges and Dartt, 2013).

Lipids

The source of lipids in the tear film is the meibomian glands embedded within the tarsal plates of each lid. The blinking process is an important mechanism in the expulsion of the secretion from the glands (Tiffany, 1995). Meibomian lipid (also known as meibum) is delivered directly as a clear oil onto the lid margins and is spread over the tear film from the inner edge of the lid margins with each blink. The thickness of the lipid layer is variable (mean thickness 42 nm, range 15–157 nm; King-Smith et al., 2000, 2010), and depending on thickness gives rise to characteristic interference patterns when viewed in specular reflection (Fig. 2.36) (Guillon, 1998). Meibomian secretion consists of a complex mixture of lipids (Table 2.3), including wax and cholesteryl esters (which together constitute approximately 70% of meibum), fatty acids and fatty alcohols (Tiffany, 1995; Butovich, 2013). The primary functions of this secretion are to

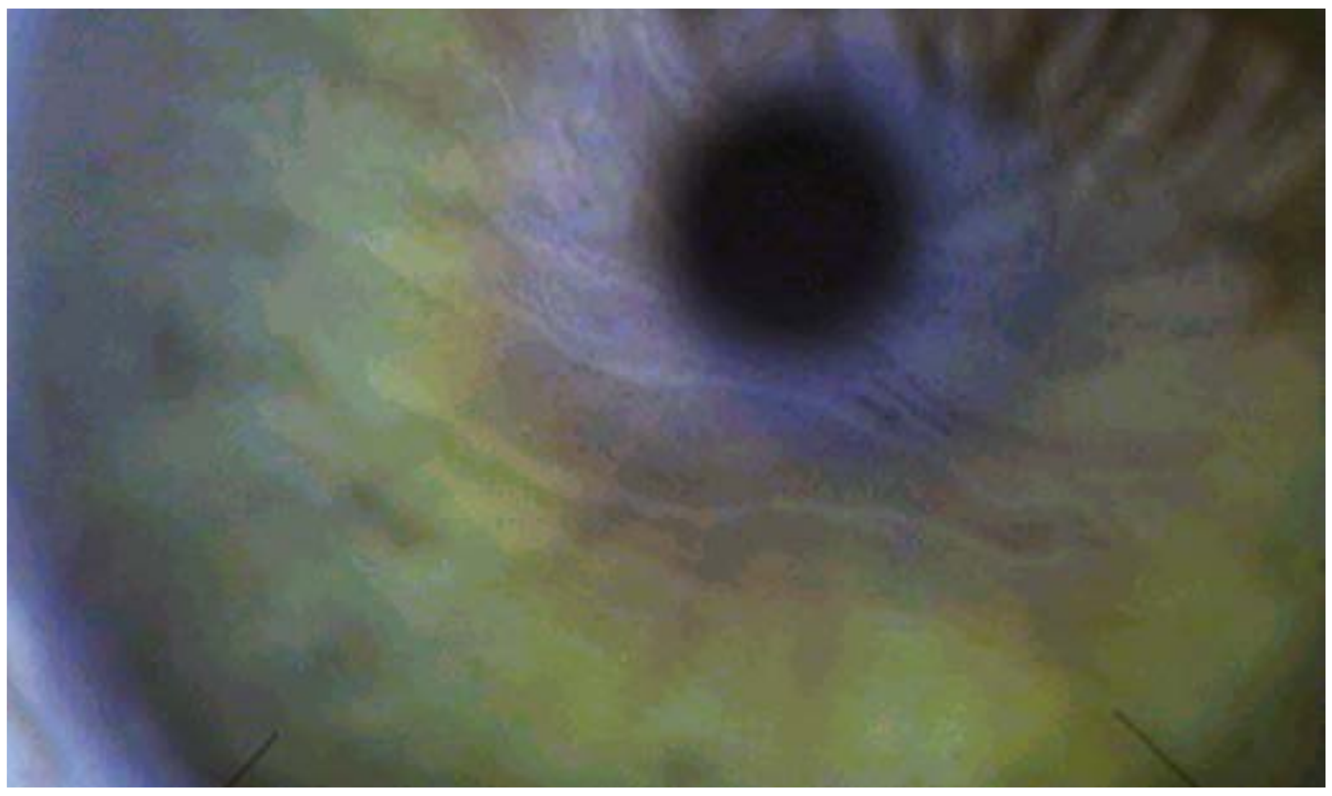

Fig. 2.36 Lipid layer of the preocular tear film viewed in specular reflection. A 'wave' appearance can be seen, which represents the most commonly observed lipid pattern in the population.

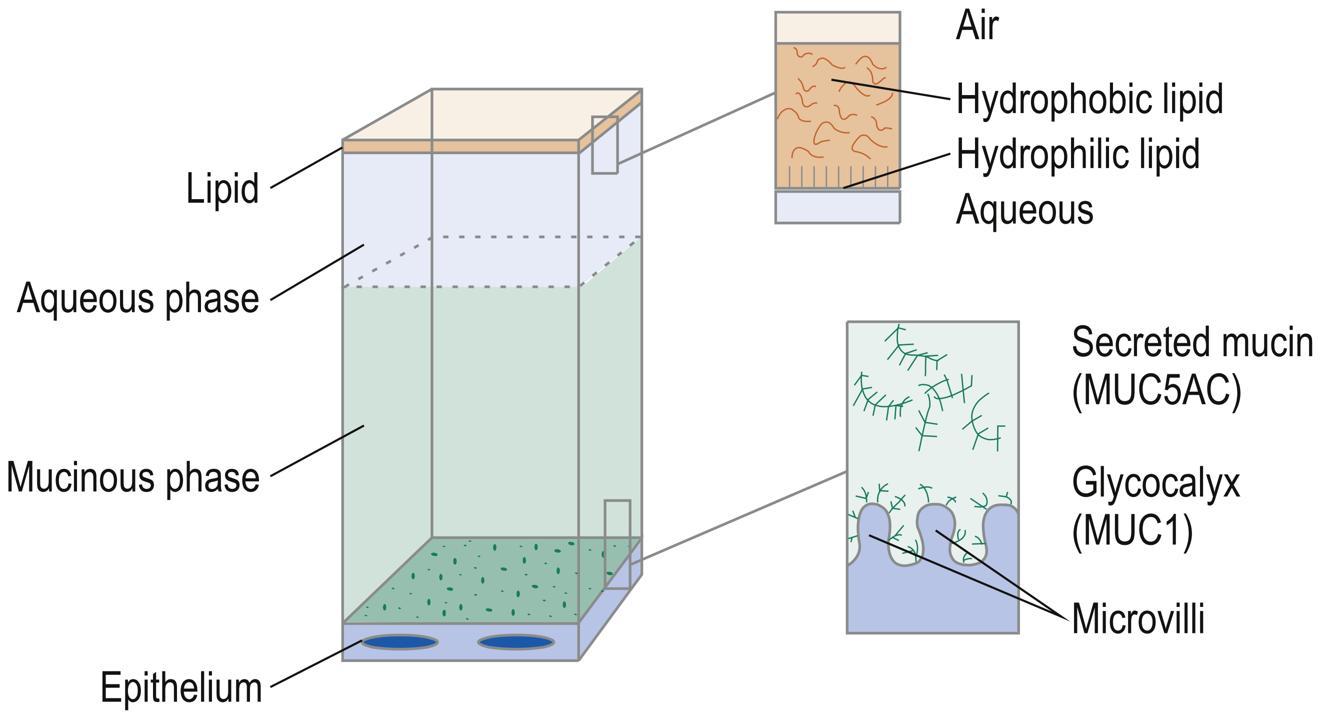

Fig. 2.37 Diagram showing the composition of the preocular tear film. Insets show details of the glycocalyx and lipid–aqueous interface. (Adapted from Corfield, A. P., Carrington, S. D., Hicks, S. J. et al. (1997). Ocular mucins: purification, metabolism and functions. Prog. Retin. Eye Res., 16, 627–656.)

provide a hydrophobic barrier at the lid margin to prevent overspill of tears, and to cover the surface of the tear film to retard evaporation (Craig and Tomlinson, 1997).

MODELS OF TEAR FILM STRUCTURE

The classical trilaminar model of tear film structure in terms of a superficial lipid layer, a middle aqueous layer and deep mucin layer, first proposed by Wolff and subsequently modified by Holly and Lemp (1977), has received broad acceptance. However, the results of recent studies have led to a re-evaluation of the nature of the aqueous and mucinous layers. Several pieces of evidence have suggested that the mucin contribution to the tear film is much greater than was previously thought (Prydal et al., 1992), and an alternative tear film model, which possesses a substantial mucinous phase, has been proposed (Fig. 2.37). The nature of the mucinous phase has not been fully established, but is thought to consist of a mixture of soluble and gel-forming mucins (Hodges and Dartt, 2013).

Conclusion

It is clear from the above account that our understanding of the structure and function of the anterior eye is far from complete, which places certain limits on our understanding of clinical, contact-lens-related phenomena. It is essential, therefore, that future research continues to focus on fundamental aspects of ocular anatomy and physiology, as well as on the more applied clinical applications that are described in the remainder of this book.

Access the complete references list online at http://www.expertconsult.com.

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3

Visual Optics

W NEIL CHARMAN

Introduction

The human eye is a remarkable optical instrument (Navarro, 2009; Artal, 2014). Its performance has been honed by millennia of evolution to meet admirably the needs of the neural system that it serves. At its best, few human-engineered photographic lens systems can match its semifield of more than 90°, its range of *f*-numbers from about *f*/11 to better than *f*/3, and its near diffraction-limited axial performance when stopped down under photopic light levels. Moreover, the focus of the eye of the young adult can be adjusted with reasonable accuracy for distances between about 0.1 m and infinity. Nevertheless, all eyes suffer from a variety of regular and irregular aberrations, while a substantial subset displays clinically significant spherical and astigmatic refractive errors. In addition, the ability to change the power of the crystalline lens to view near objects is an asset that declines with age, to disappear entirely by the mid 50s, when presbyopia is reached.

The invention of spectacles in the 13th century, and their subsequent relatively slow refinement, followed by the more rapid development of contact lenses in the 20th century, has done much to provide solutions to the problems of both refractive error and presbyopia: improvements in the design of both types of lens continue to be made. Refractive surgical techniques, including both laser-based methods that modify the corneal contour and intraocular lenses, are beginning to compete with spectacle and contact lens corrections, although unanswered questions still remain concerning the long-term efficacy and safety of some of the procedures used. In this chapter the basic optics of the eye and its components will first be reviewed. This will be followed by a discussion of the modifications that the correction of refractive error – particularly by contact lenses – produces in factors such as spectacle magnification, accommodation and convergence (Douthwaite, 2005).

The Basic Optics of the Eye and Ametropia

GENERAL OPTICAL CHARACTERISTICS

The familiar, and deceptively simple, optical layout of the eye is shown in Fig. 3.1.

About three-quarters of the optical power comes from the anterior cornea, with the crystalline lens providing supplementary power that, in the pre-presbyope, can be varied to focus sharply on objects at different distances. The actual optical design is, however, subtle, in that all the optical surfaces are aspheric, while the lens, and probably also the cornea, displays a complex gradient of refractive index. There is little doubt that such refinements play an important role in controlling aberration.

The distribution across the population of parameters such as surface radii, component spacing and refractive indices has been studied by a variety of authors (McBrien and Barnes, 1984; Charman, 2010). Refractive indices of the media vary little between eyes, apart from the non-uniform refractive index distribution within the lens, which changes with age as the lens grows throughout life (Pierscionek et al., 1988; Pierscionek, 1995; Jones et al., 2005; Kasthurirangan et al., 2008). Each dimensional parameter appears to be approximately normally distributed amongst different individuals (Stenstrom, 1946; Sorsby et al., 1957). The values of the different parameters in the individual eye are, however, correlated so that the resultant distribution of refractive error is strongly peaked near emmetropia, rather than being normal (Fig. 3.2).

This correlation is thought to be due to a combination of genetic and environmental factors; visual experience helping to 'emmetropize' the eyes actively (Troilo, 1992; Saunders, 1995; Wildsoet, 1997; Weale, 2003; Mutti, 2010; Flitcroft 2014). The apparently greater incidence of myopia in recent times has been attributed to the greater prevalence of near tasks and other changes in environment and lifestyle (Rosenfield and Gilmartin, 1998; Pan et al., 2011).

MODEL EYES AND AMETROPIA

Many authors have produced paraxial models of the emmetropic eye, based on typical measured values of the ocular parameters (Thibos and Bradley, 1999; Atchison and Smith, 2000; Rabbetts, 2007; Atchison, 2009). These simplify the optical complexities of the real eye while having approximately the same basic imaging characteristics. Some examples are given in Table 3.1; fuller details of these and other more elaborate eye models (e.g. Goncharov and Dainty, 2007) are given in the cited references.

Using the parameters of the model eyes it is straightforward to calculate the positions of the cardinal points, which, in thick-lens theory, can be used to summarize paraxial imagery (Fig. 3.3).

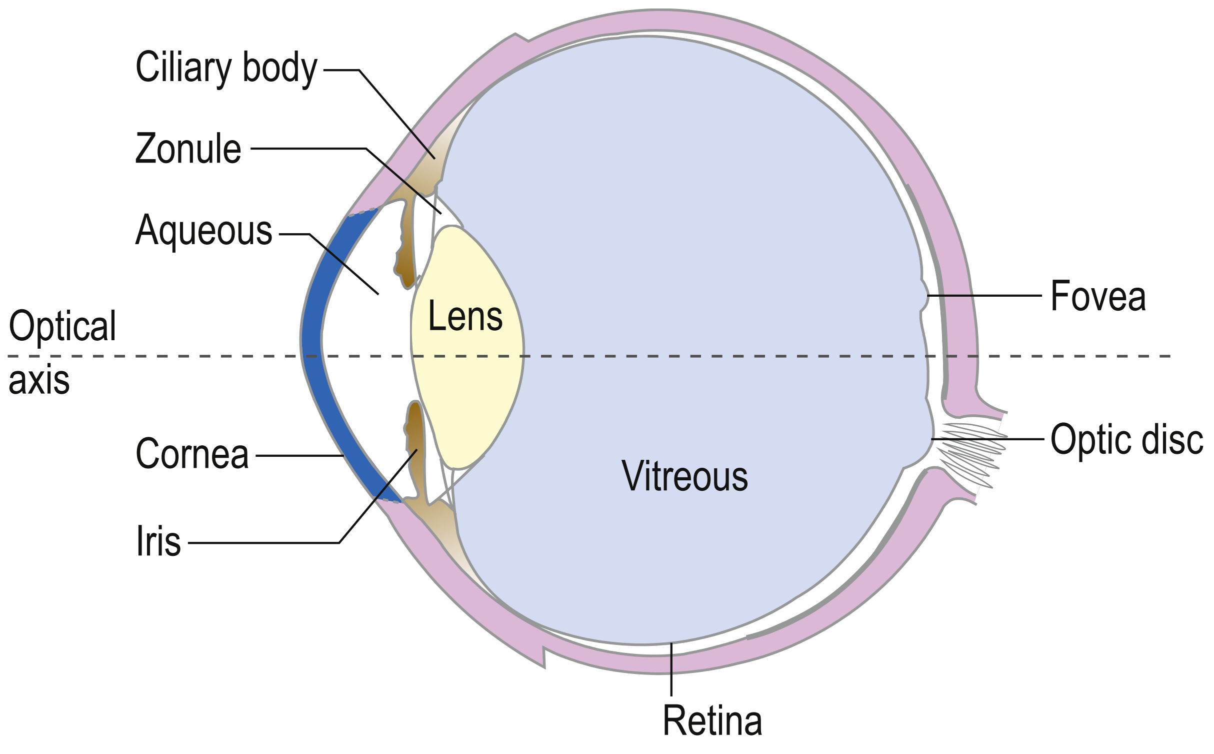


Fig. 3.1 Schematic horizontal section of the human eye.

It is, however, important to stress that these eye models are only representative. In practice, an eye of shorter or longer axial length may still be emmetropic. This behaviour and the various possible origins of refractive error are easy to understand in terms of these basic models. Consider, for simplicity, the generic reduced eye shown in Fig. 3.4, with a single refractive surface of radius r, refractive index n′ and axial length k′. The power of the eye, F_e, is given by:

$$F_e = (n' - 1)/r$$

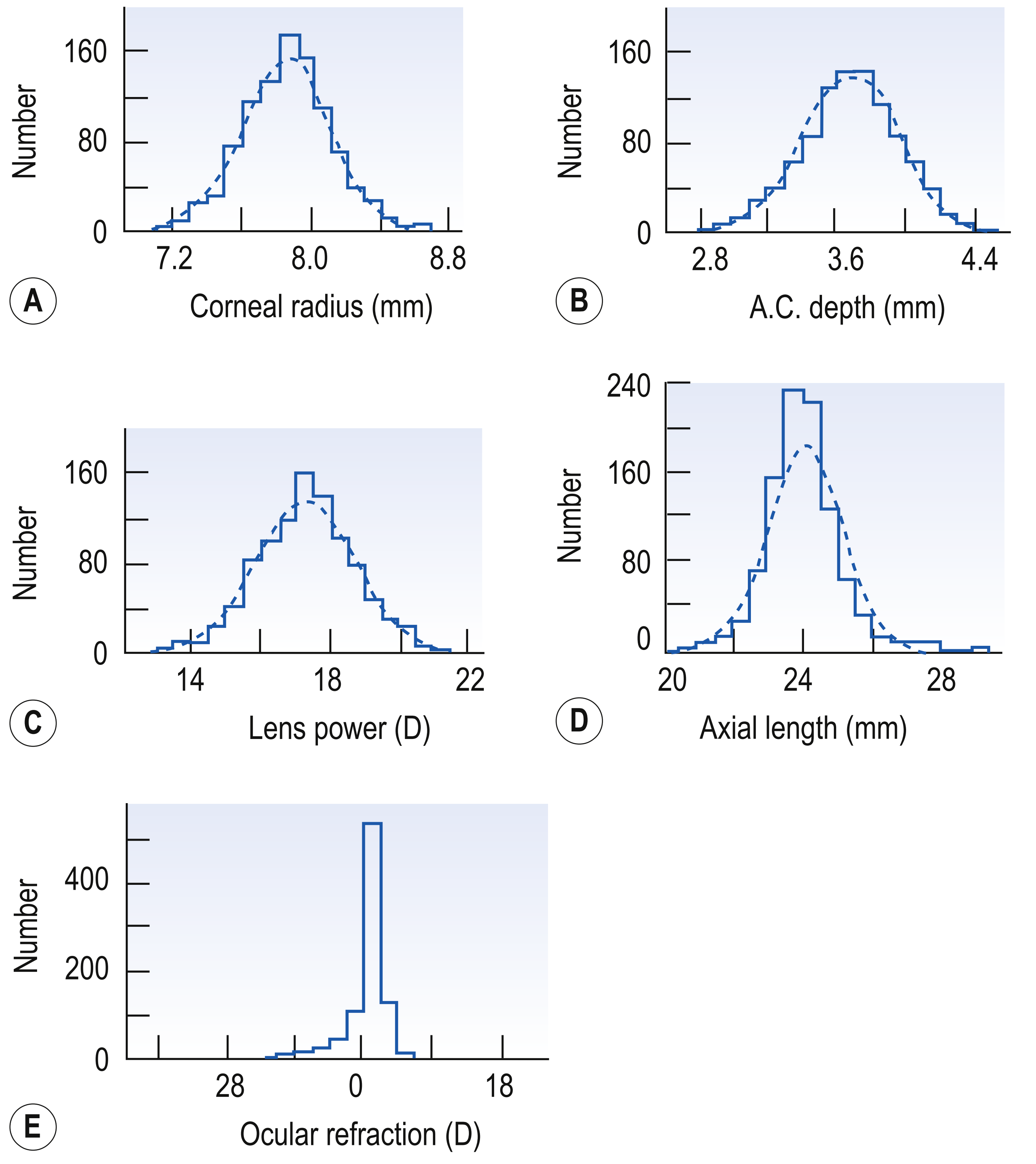


Fig. 3.2 Distribution of some ocular parameters and of refractive error. (A) Radius of curvature of the anterior cornea. (B) Anterior chamber (A.C.) depth. (C) Lens power. (D) Axial length. (E) Spherical equivalent refractive error. In (A)–(D) the dashed curve represents the corresponding normal distribution. Note that, whereas individual parameters are distributed approximately normally, refractive errors are strongly peaked near emmetropia. (After Stenstrom, S. (1946). Untersuchungen uber der Variation und Kovaration der optische Elemente des menschlichen Auges. Acta Ophthalmol., 15(Suppl. 26). [Translated by Woolf, D.])

For a distant object (zero object vergence) the image vergence n'/l' equals F_e. For emmetropia we require that the image of the distant object lies on the retina, i.e. $l'=k'$, implying that $F_e=n'/k'=K'$, where $K'=n'/k'$ is the dioptric length of the eye. There are, then, in principle an infinite number of matching pairs of values of F_e and K′ that lead to emmetropia, so that eyes that are relatively larger or smaller than the 'standard' models may still be emmetropic.

In the case of ametropia F_e and K′ are no longer equal. If the power of the eye is too high ($F_e>K'$) we get myopia; if too low ($F_e<K'$) we get hypermetropia. The ocular refraction K is given by:

$$K = K' - F_e$$

Thus, for example, myopia (K negative) can occur if K′ is too low, corresponding to an axial length k′ that is relatively too great (axial ametropia), or if F_e is relatively too large (refractive ametropia). A high F_e may arise as a result of either too small a corneal radius r or because n′ is too large (note, however, that changes in n′ affect both F_e and K′). Although more sophisticated eye models are characterized by more parameters, the possible origins of ametropia are essentially the same.

Astigmatism can arise either because one or more of the optical surfaces is toroidal or because of tilts of surfaces with respect to the axis, particularly of the lens.

How accurate do our models and associated calculations have to be? Although in the laboratory it may theoretically be possible to measure all the parameters of an individual eye, in general all that will be known in the consulting room is that the eye is ametropic. Thus, in clinical contact lens practice, precise calculation of the optical effects in the uncorrected or corrected eye is rarely possible; it is more important that the general magnitude of the effects be borne in mind and that the approximate changes brought about by correction be fully understood.

ACCOMMODATION AND THE PRECISION OF OCULAR FOCUS

The decline with age in the subjective amplitude of accommodation (i.e. the reciprocal of the distance, measured in metres, of the nearest point at which vision remains subjectively clear to the distance-corrected patient) is illustrated in Fig. 3.5A.

Few everyday tasks require accommodation in excess of about 4 D, so that it is normally only as individuals approach 40 years of age that marked problems with near vision start to appear. It is, however, important to recognize that, even for objects lying

TABLE 3.1 Parameters of Some Paraxial Models of the Human Eye

		Schematic Eye (mm)	Simplified Schematic Eye (mm)	Reduced Eye (mm)
Surface radii (mm)	Anterior cornea	7.80	7.80	5.55
	Posterior cornea	6.50	—	—
	Anterior lens	10.20	10.00	—
	Posterior lens	−6.00	−6.00	—
Distances from Anterior Cornea (mm)	Posterior cornea	0.55	—	—
	Anterior lens	3.60	3.60	—
	Posterior lens	7.60	7.20	—
	Retina	24.20	23.90	22.22
Refractive Indices	Cornea	1.3771	—	—
	Aqueous humour	1.3374	1.333	1.333
	Lens	1.4200	1.416	—
	Vitreous humour	1.3360	1.333	—

(Data from Charman, W. N. (1991) Optics of the human eye. In W. N. Charman (ed.) Vision and Visual Dysfunction. Vol. 1: Visual Optics and Instrumentation (pp. 1–26). London: Macmillan.)

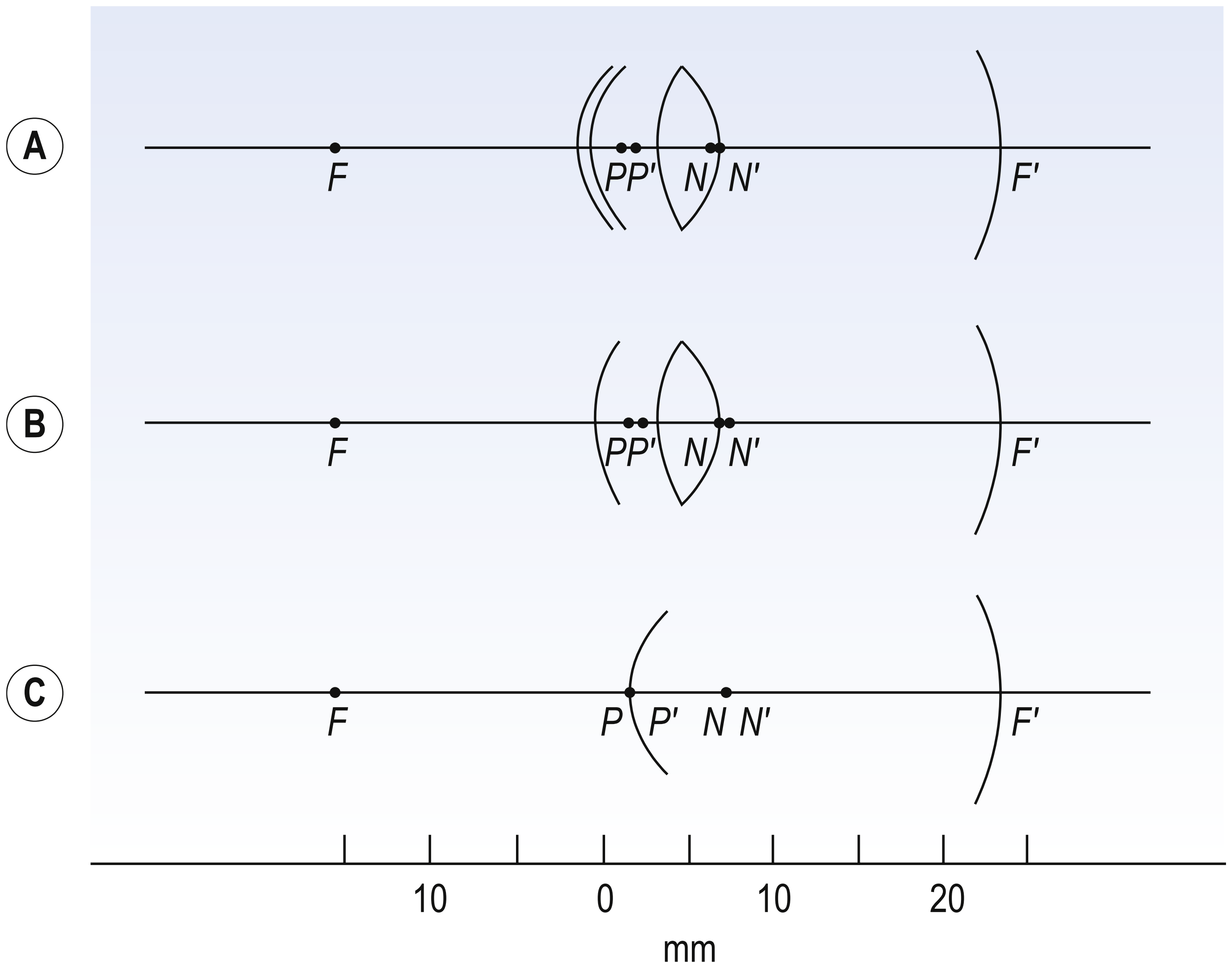


Fig. 3.3 Examples of paraxial models of the human eye. In each case F and F′ represent the first and second focal points, respectively, P and P′ the first and second principal points, and N and N′ the first and second nodal points. (A) Unaccommodated schematic eye with four refracting surfaces. (B) Simplified, unaccommodated eye with three refracting surfaces. (C) Reduced eye with a single refracting surface. (Adapted from Charman, W. N. (1991). Optics of the human eye. In W. N. Charman (ed.) Vision and Visual Dysfunction. Vol. 1: Visual Optics and Instrumentation (pp. 1–26). London: Macmillan.)

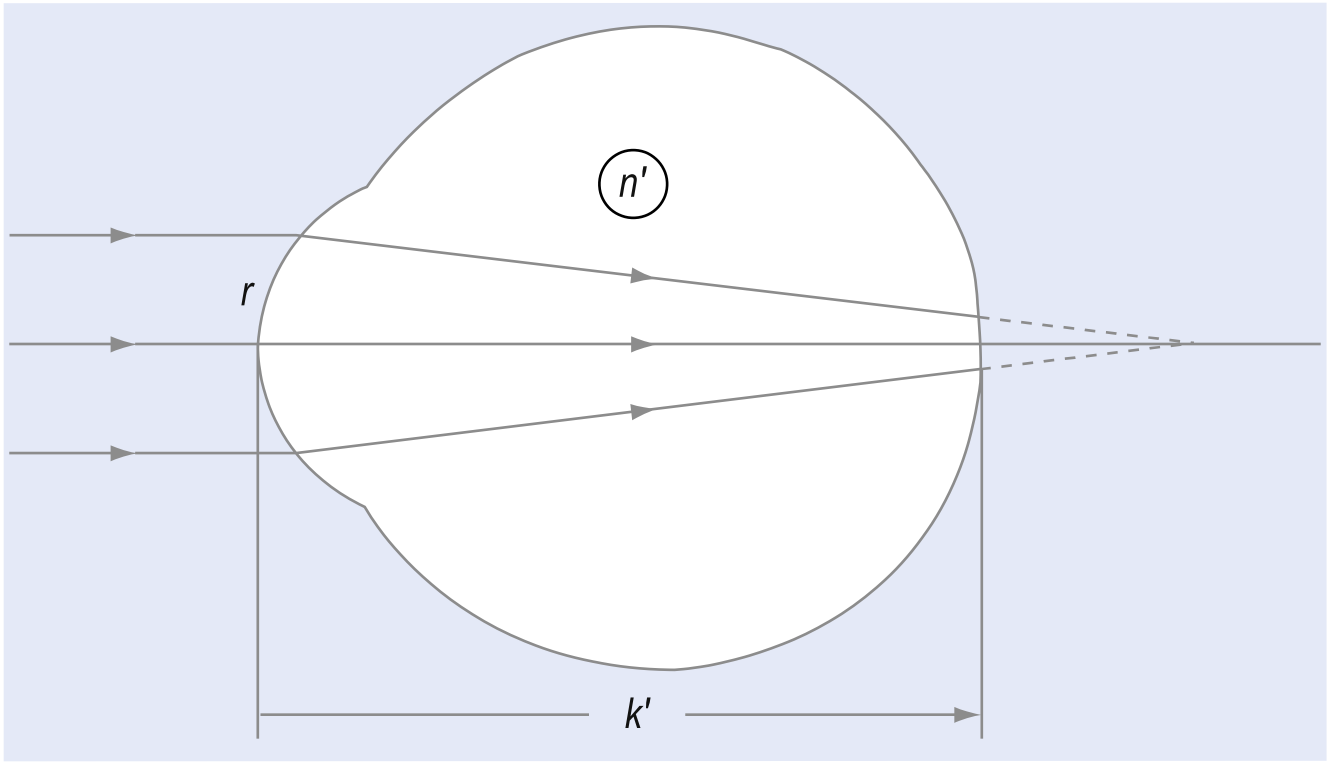


Fig. 3.4 A generic reduced eye model, with parameters as indicated. r is the radius of curvature of the refracting surface, k′ the axial length and n′ the refractive index. The eye shown is hypermetropic.

within the available range of accommodation, accommodation is rarely precise. 'Lags' of accommodation usually occur in near vision and 'leads' for distance vision (Fig. 3.5B). As the accommodation system is driven via the retinal cones, these lags increase if the environmental illumination is reduced to mesopic levels and the accommodation system is effectively inoperative at scotopic light levels, when the system reverts to its slightly myopic (around −1 D) tonic level (Ciuffreda, 1991, 1998).

Corneal Topography

It has already been stated that the optical surfaces of the eye are not necessarily spherical. The topography of the anterior cornea is of particular interest since, as the dominant refractive surface, its form has a major influence on overall refractive error and ocular aberration. In contact lens work, it is of enormous importance to the fitting geometry.

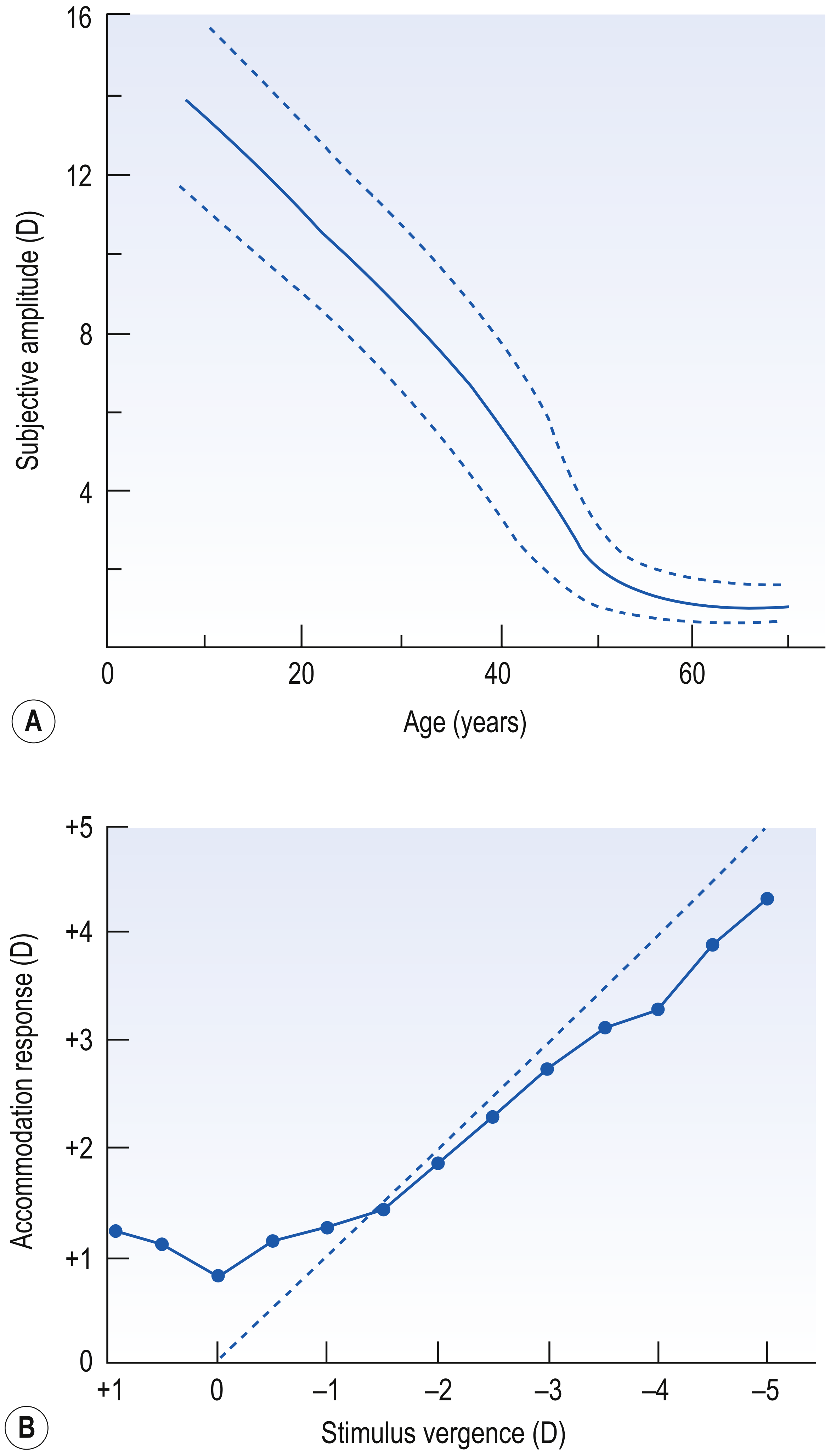


Fig. 3.5 (A) The decline in monocular subjective amplitude of accommodation, referenced to the spectacle plane, with age. (B) Typical steady-state accommodation response / stimulus curve, showing lags of accommodation for near stimuli. (Data in (A) from Duane, A. (1922). Studies in monocular and binocular accommodation with their clinical implications. Am. J. Ophthalmol., 5, 865–877.)

We have already seen (see Fig. 3.2A) that the radius of curvature over the central region, as measured by conventional keratometers, shows considerable individual variation, and it has been recognized for more than a century that many corneas display marked astigmatism. Corneal astigmatism is not, of course, necessarily equal to the total ocular astigmatism, as additional astigmatism (residual astigmatism) may be contributed by the crystalline lens.

Earlier work on corneal topography using modifications of traditional keratometers concentrated on approximating the form of the corneal surface by a conicoid, in which each meridian is a conic section. In this approach the anterior corneal surface can be described by the following equation (Bennett, 1966, 1988):

$$x^2 + y^2 + pz^2 = 2r_0z$$

where the coordinate system has its origin at the corneal apex, z is the axial coordinate, r_0 is the radius of curvature at the cornea apex and the shape factor p is a constant parameter characterizing the form of the conic section for the individual eye. Values of $p<0$ represent hyperboloids, $p=0$ paraboloids, $0<p<1$ flattening (prolate) ellipsoids, $p=1$ spheres and $p>1$ steepening (oblate)

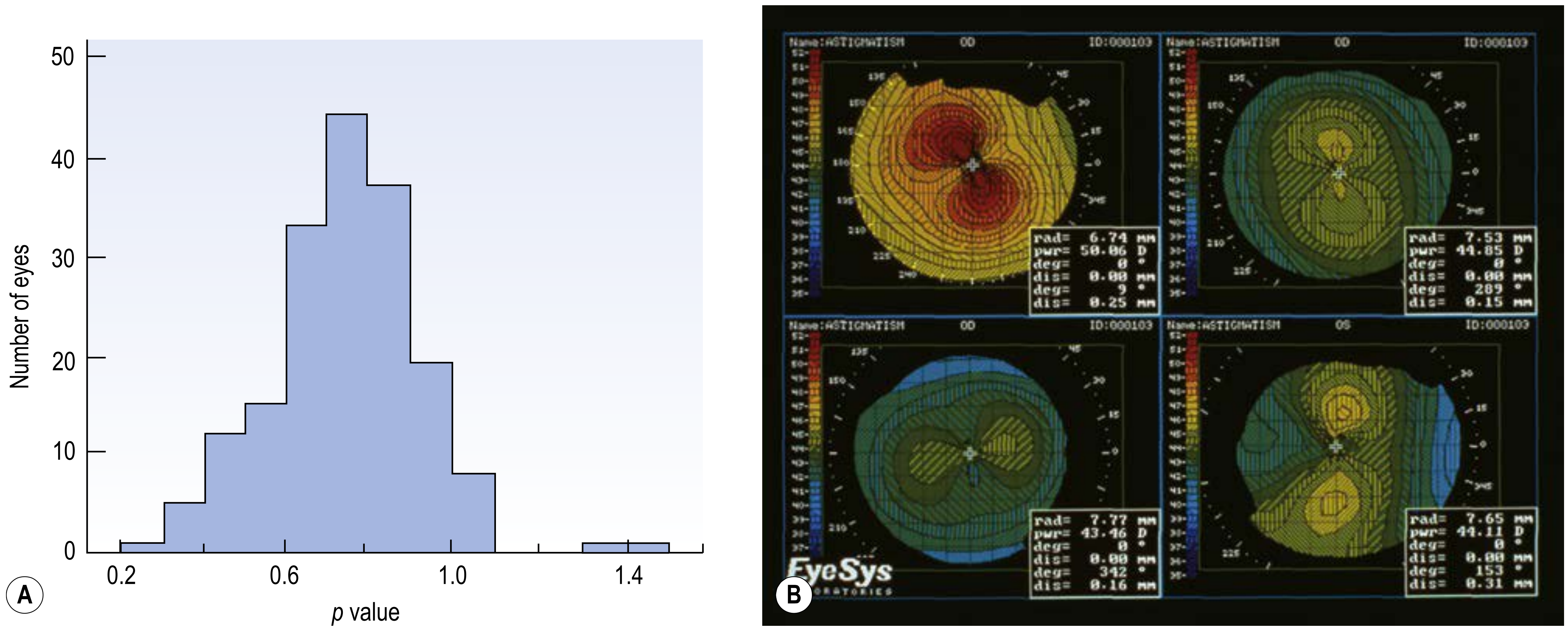


Fig. 3.6 (A) Histogram showing the distribution of the shape factor, p, in 176 eyes. (B) Typical result from a topographic instrument, showing the local variation in nominal spherical power across four astigmatic corneas. (Adapted from Kiely, P. M., Smith, G. & Carney, L. G. (1982). The mean shape of the human cornea. Optica Acta, 29, 1027–1040.)

ellipsoids. The same equation is sometimes written in terms of the Q-factor or the eccentricity e of the conic section, where:

$$p = 1 + Q = 1 - e^2$$

Kiely et al. (1982) found mean r_0 and p values of 7.72 ± 0.27 mm and 0.74 ± 0.18, respectively, these values being supported by the results of Guillon et al. (1986), that is, 7.85 ± 0.25 mm and 0.85 ± 0.15; broadly similar p values are found in different racial groups: 0.70 ± 0.12 in Chinese eyes (Zhang et al., 2011) and 0.74 ± 0.19 in Afro-Americans (Fuller and Alperin, 2013). Thus the typical general form of the cornea is that of a flattening ellipsoid, with the curvature reducing in the periphery (Fig. 3.6A).

Recent years have seen the introduction of a range of topographic instruments, marrying optical with electronic and computer technology, that can routinely give a much fuller picture of the corneal contour (see Chapters 36, 41). These videokeratographic and scanning-slit results show that the conicoidal model is only a first approximation to corneal shape and that individual eyes show a wide range of individual asymmetries. In particular, the rate of corneal flattening is often different in different meridians (Fig. 3.6B), while the corneal cap of steepest curvature may be displaced with respect to the visual axis, on average lying about 0.8 mm below (Mandell et al., 1995). More elaborate models have been devised to describe these asymmetries in corneal shape (Navarro et al., 2006)

Currently the most popular form of output for the topographic data is probably a colour-coded map of the cornea, showing regions of different axial (sagittal) power (see Chapter 36). This may be slightly misleading, since each local area of the cornea is toroidal rather than spherical. For this reason both sagittal and tangential power maps are often used (Mountford et al., 2004). It is possible that other forms of representation, such as those that plot local departures in height from a best-fitting sphere, will ultimately prove more useful, particularly in relation to the fitting of rigid contact lenses (Salmon and Horner, 1995; Horner et al., 1998). The contribution of the cornea to the overall ocular wave aberration can be deduced from the videokeratogram (Hemenger et al., 1995; Guirao and Artal, 2000). Scanning slit instruments, such as the Orbscan and Pentacam, allow the form of the posterior surface of the cornea to be deduced, as well as that of the anterior surface (see Chapters 36, 41).

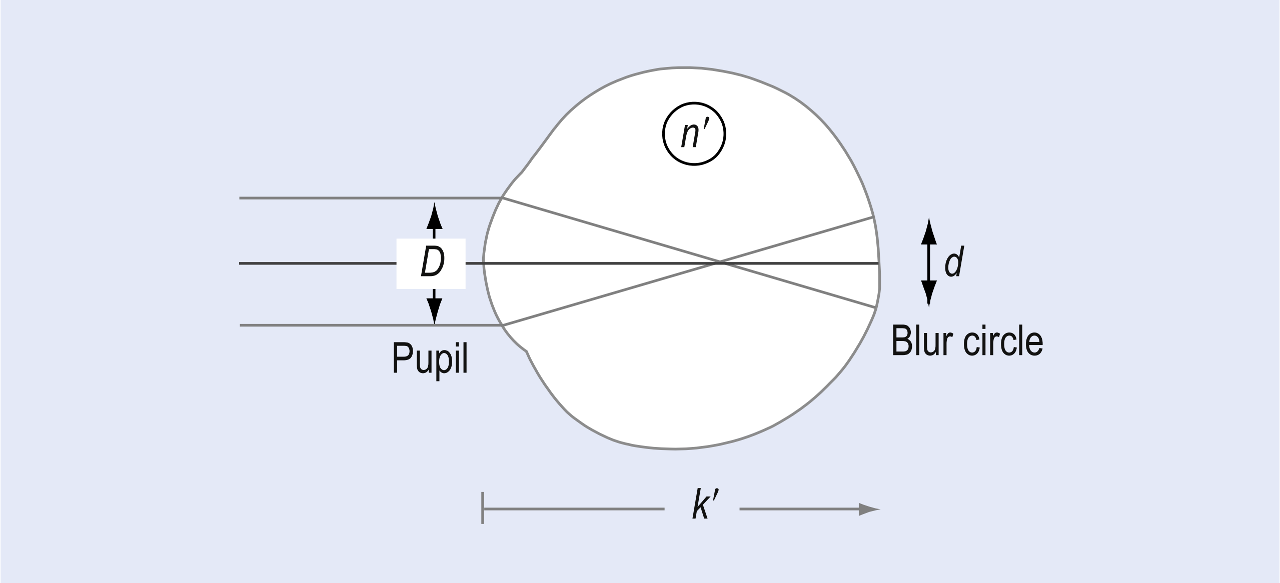


Fig. 3.7 Formation of the retinal blur circle for a myopic eye. D is the pupil diameter and d is the blur circle diameter.

Pupil Diameter and Retinal Blur Circles

As will be discussed below, although the retinal image is always blurred by both aberration and diffraction, in ametropia and presbyopia it is often defocus blur that is the major source of degradation. Defocus will occur whenever the object point lies outside the range of object distances embraced by the far and near points of the individual. As noted earlier, even within this range, small errors of focus will normally occur owing to the steady-state errors that are characteristic of the accommodation system. Using a reduced eye model and simple geometric optical approximations (Smith, 1982, 1996; Atchison and Smith, 2000; Rabbetts, 2007) – which are normally valid for all errors of focus over about 1 D – such blur depends on the dioptric error of focus and the pupil diameter. From Fig. 3.7 it can be seen that, for any object point and assuming that the eye pupil is circular, spherical defocus produces a 'blur circle' on the retina.

Using similar triangles, it is easy to show that the diameter (d, in mm) of this blur circle is:

$$d = \Delta F D / K'$$

where ΔF is the dioptric error of focus with respect to the object point, D is the pupil diameter in millimetres and K′ is the dioptric length of the eye. If astigmatism is present, the blur patch is an ellipse, with major and minor axes corresponding to the focus errors in the two principal meridians.

We can express the blur circle diameter in angular terms as:

$$\alpha = \Delta FD\ 10^{-3}\ \text{rads} = 3.44\Delta FD\ \text{min arc} \qquad \text{Eq. 3.1}$$

Thus, for a 3 mm diameter pupil, the blur circle diameter increases by roughly 10 min arc per dioptre of defocus. Chan et al. (1985) measured blur circle diameters experimentally and found that results for pupil diameters between 2 and 6 mm and defocus between 1 and 12 D were quite accurately predicted by Eq. 3.1.

The impact of blur on visual acuity depends somewhat on the acuity target chosen and the criteria and observation conditions used. We would expect the minimum angle of resolution (MAR) to be somewhat smaller than the blur circle diameter. Smith (1996) suggests that, for errors of focus above about 1 D, letter targets, a 50% recognition rate, and normal chart luminances of about 150 cd/m² (giving pupil diameters of about 4 mm):

$$\text{MAR} = 0.65\Delta FD\ \text{min arc} \qquad \text{Eq. 3.2}$$

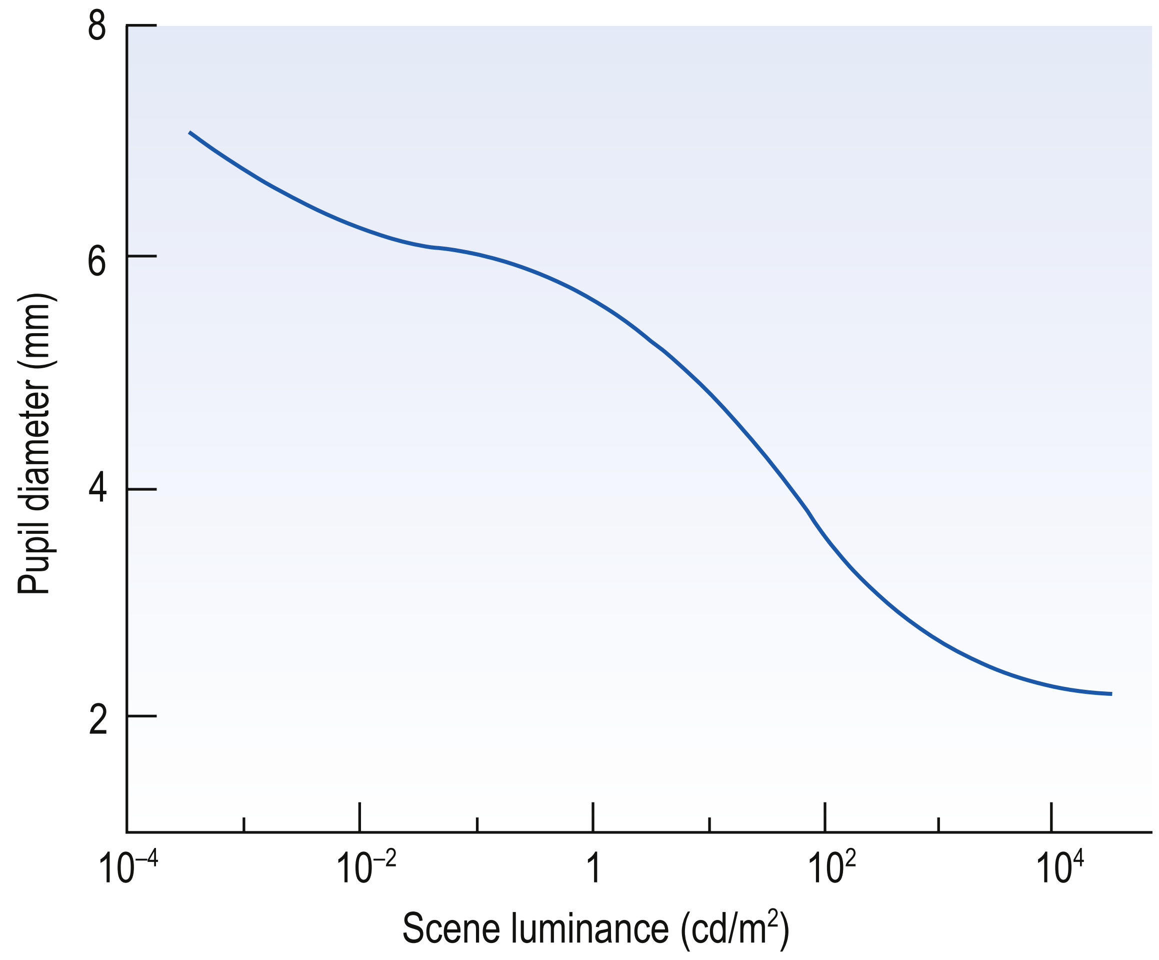


Fig. 3.8 Dependence of pupil diameter on field luminance in young adults. (Adapted from Farrell, R. J. & Booth, J. M. (1984). Design Handbook for Imagery Interpretation Equipment (Sec. 3.2, p. 8). Seattle, WA: Boeing Aerospace Co.)

With errors of focus smaller than about 1 D, diffraction, aberration and the neural capabilities of the visual system are more important than defocus blur and the MAR exceeds that predicted by Eq. 3.2.

The natural pupil diameter is chiefly dependent on the ambient light level. Fig. 3.8 shows typical results for this relationship in young adults.

Pupil diameters at any light level tend to decrease with age (senile miosis: Winn et al., 1994) and with accommodation, as well as varying with a variety of emotional and other factors (Loewenfeld, 1998). Some typical values for older eyes under different lighting conditions are given in Table 3.2.

Clearly, reducing the pupil size results in smaller amounts of blur in the retinal image for any given level of defocus, and thus the depth of focus is increased. For example, an uncorrected low myope may experience minimal levels of distance blur under good photopic levels of illumination but may notice considerable blur when driving at night, when the pupil is large. Pupil diameter strongly influences the design and performance of bifocal and other types of contact lens for the presbyope (Koch et al., 1991; see Chapter 23).

Effects of Diffraction and Aberration

As noted above, these are chiefly important when the eye is close to its optimal focus. The point image for a spherical error of focus then no longer approximates to a blur circle (or a point in the absence of defocus) but has more complex form.

DIFFRACTION

If the optical performance of the eye were limited only by diffraction, the in-focus retinal image of a point object would be an Airy diffraction pattern. The angular radius of the first dark ring in this pattern would be:

$$\theta_{\min} = 1.22\lambda/D\ \text{radians} = 4194\lambda/D\ \text{min arc}$$

where the wavelength λ and the pupil diameter D are expressed in the same units. It is usually assumed that it will be possible to resolve the images of two identical point objects if their angular separation equals this value (the Rayleigh limit).

TABLE 3.2 Means, Standard Deviations and (Bracketed) Ranges of Pupil Diameter in Various Visual Tasks and Illuminances for Presbyopic Patients of Different Ages

Condition	Pupil Diameter Ages 40–49 (mm)	Pupil Diameter Ages 50–59 (mm)
Night driving	5.2 ± 0.8 (3.8–6.2)	4.6 ± 0.8 (3.1–5.8)
Reading (low illumination, 215 lux)	3.5 ± 0.6 (2.16–4.6)	3.0 ± 0.5 (2.3–4.4)
Reading (high illumination, 860 lux)	2.9 ± 0.5 (2.2–3.9)	2.6 ± 0.3 (2.1–3.6)
Outdoors (indirect sunlight, 3400 lux)	2.7 ± 0.5 (1.9–3.4)	2.5 ± 0.4 (1.9–3.4)
Outdoors (direct sunlight, 11 000 lux)	2.3 ± 3.4 (1.8–3.1)	2.2 ± 0.3 (1.8–2.9)

(Data from Koch D. D., Samuelson S. W., Haft E. A. & Merin L. M. (1991). Pupillary size and responsiveness. Implications for selection of a bifocal intraocular lens. Ophthalmology, 98, 1030–1035.)

MONOCHROMATIC ABERRATIONS

Aberration obviously acts to introduce additional blur into both in-focus and out-of-focus images. Monochromatic aberration can arise from a variety of causes. The eye would be expected to display the classical Seidel aberrations (spherical aberration, coma, oblique astigmatism, field curvature and distortion) inherent in any system of spherical centred surfaces but, due to the various asphericities, tilts, decentrations and irregularities that may occur in its optical surfaces (see Fig. 3.6B), its aberrational behaviour is much more complex than that which would be expected on the basis of simple schematic eye models of the type illustrated in Fig. 3.3 and Table 3.1.

Early authors attempted to analyse ocular aberration in terms of the individual Seidel aberrations. However, these attempts were of limited value because of the lack of rotational symmetry in the system. Monochromatic aberration is now most commonly expressed in terms of the wavefront aberration (Atchison, 2004; Charman, 2005). The behaviour of a 'perfect' optical system, according to geometrical optics, can be visualized either as involving rays radiating from an object point to be converged to a unique image point, or as spherical wavefronts diverging from the object point to converge at the image point, so that the object point is the centre of curvature of the object wavefronts and the image point is that of the image wavefronts (Fig. 3.9A).

The rays and wavefronts are everywhere perpendicular to one another. If we have aberration, the image rays fail to intersect at a single image point. Similarly, the wavefronts, which are still everywhere perpendicular to the rays, are no longer spherical (Fig. 3.9B). It is usual to express the wavefront aberration at any point in the pupil as the distance between the ideal spherical wavefront, centred on the gaussian image point, and the actual wavefront, where both are selected to coincide at the centre of the exit pupil (Fig. 3.9C).

Recent years have seen an explosion of interest in ocular aberrations, largely fuelled by the realization that the earlier excimer-laser refractive surgical techniques often resulted in poor vision because these procedures introduced unacceptably high levels of aberration. As a result, a variety of commercial aberrometers have become available for measuring the wavefront aberration of the eye (Krueger et al., 2004; Atchison, 2005). One of the more elegant designs involves the use of a Hartmann–Shack wavefront sensor (Liang et al., 1994, 1997; Liang and Williams, 1997). A regular array of identical microlenses allows the slope of the wavefront across a lattice of points in the pupil to be determined. The principle can be understood with reference to Fig. 3.10.

Suppose we have a point source on the retina of a perfect emmetropic eye. The light leaving the eye can be envisaged either as a bundle of parallel rays or as a series of plane wavefronts (Fig. 3.10A). We now place our array of microlenses in the path of the emerging light. Evidently each lens will converge the parallel rays to its second focal point, so that in the common focal plane we shall see an absolutely regular array of image points. If now the eye suffers from aberration, the emergent rays are no longer parallel and the associated wavefronts are no longer flat (Fig. 3.10B). Thus the rays no longer come to a focus on the axes of the lenses; the lateral displacement from the focal point of each lens is directly proportional to the local inclination of the ray or the slope of the wavefront. It is, then, easy to calculate the form of the emergent wavefronts and the wavefront aberration from the distorted pattern of image points.

Examples of some typical axial results for normal eyes corrected for any spherocylindrical refractive error are shown in Fig. 3.11. The wavefront error is usually expressed in microns (micrometres).

Departures from the reference sphere (in this case of infinite radius) of more than a quarter of a wavelength (i.e. around 0.14 µm for the green region of the spectrum) would be expected to degrade image quality. What is striking is the wide variation between the aberrations shown by different eyes. The aberration in the central 2–3 mm of the pupil is usually modest, but much larger amounts may be found in the periphery of dilated pupils. On the basis of wavefront aberration results, it is possible to calculate monochromatic point and line spread functions and also the ocular modulation and phase transfer functions for any pupil diameter (Hopkins, 1962).

Note that the wavefront maps shown in Fig. 3.11 were obtained on axis with the eyes under cycloplegia. In each case, ocular aberrations get worse nearer to the peripheral pupil, as with most optical systems. In practice, the aberrations on the visual axis of each individual eye vary slightly with time owing

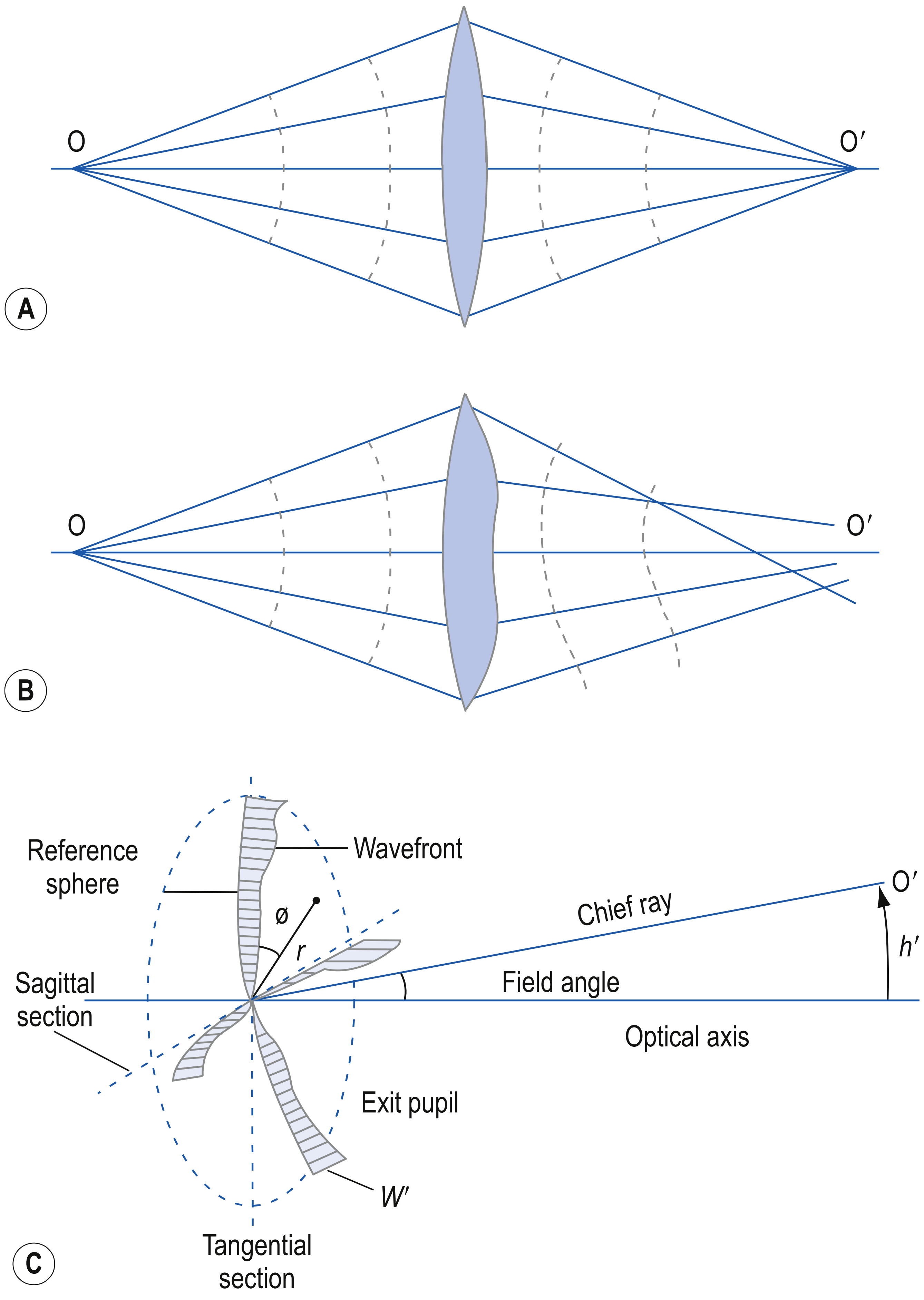


Fig. 3.9 (A) With a perfect lens, rays from the object (O) converge to a single image point. Alternatively we can visualize divergent spherical wavefronts (shown as dashed lines) from the object point converging as spherical wavefronts to the image point. (B) If the lens suffers from aberration, the imaging rays fail to converge to a single point and the corresponding wavefronts are not spherical. (C) The wavefront aberration, W′, is specified as the distance between the ideal wavefront, or reference sphere, centred on the gaussian image point, O′, and the actual wavefront in the exit pupil. It is usually adjusted to be zero at the centre of this pupil.

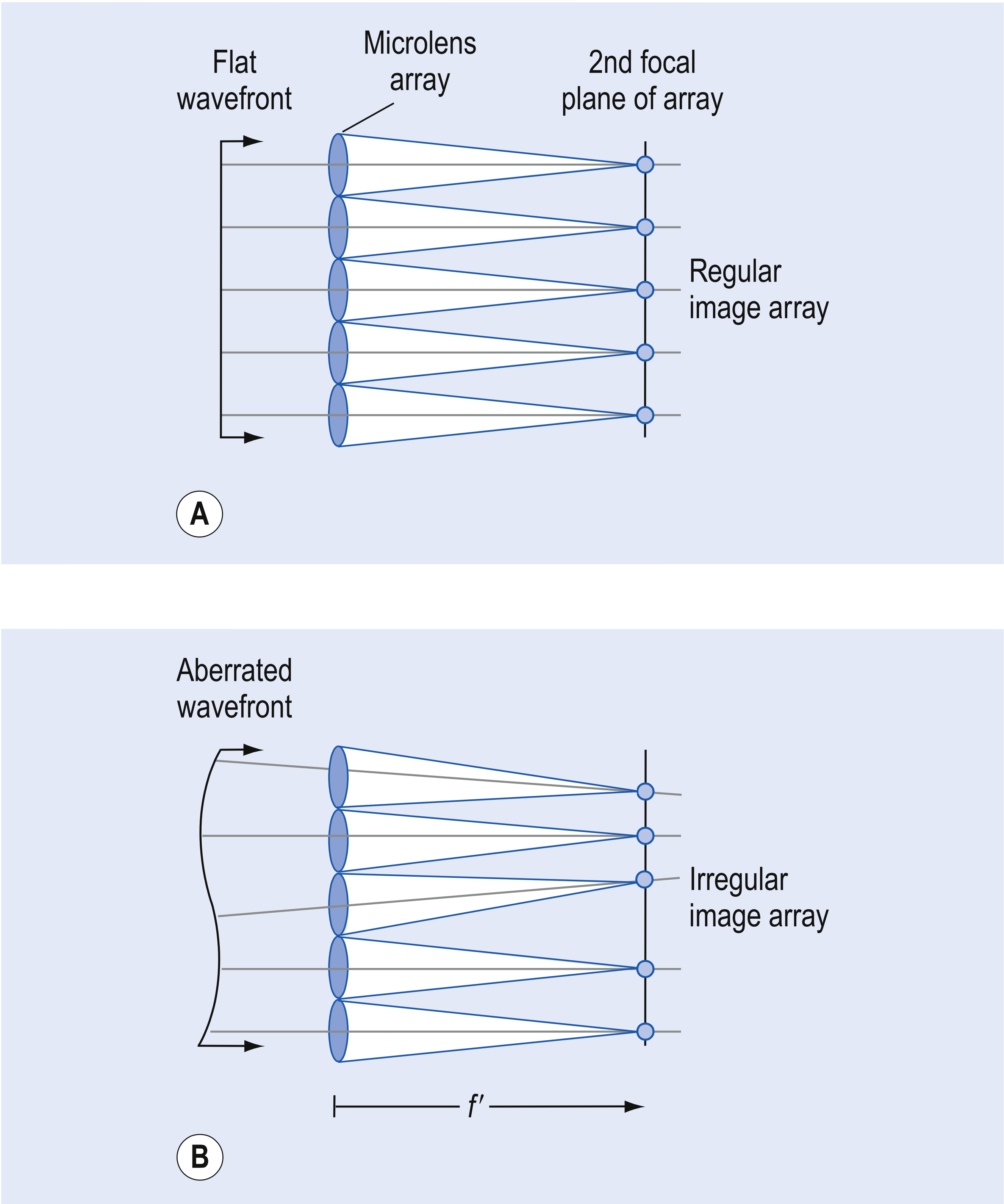


Fig. 3.10 Principle of the Hartmann–Shack technique. (A) Effects with a perfect emmetropic eye, where the images are formed on the axis of each microlens and hence are regularly spaced. (B) Effects with an aberrated eye, where the image array is irregular as the images are no longer formed on the axes of the lenses (see text). f′ is the focal length of the microlenses.

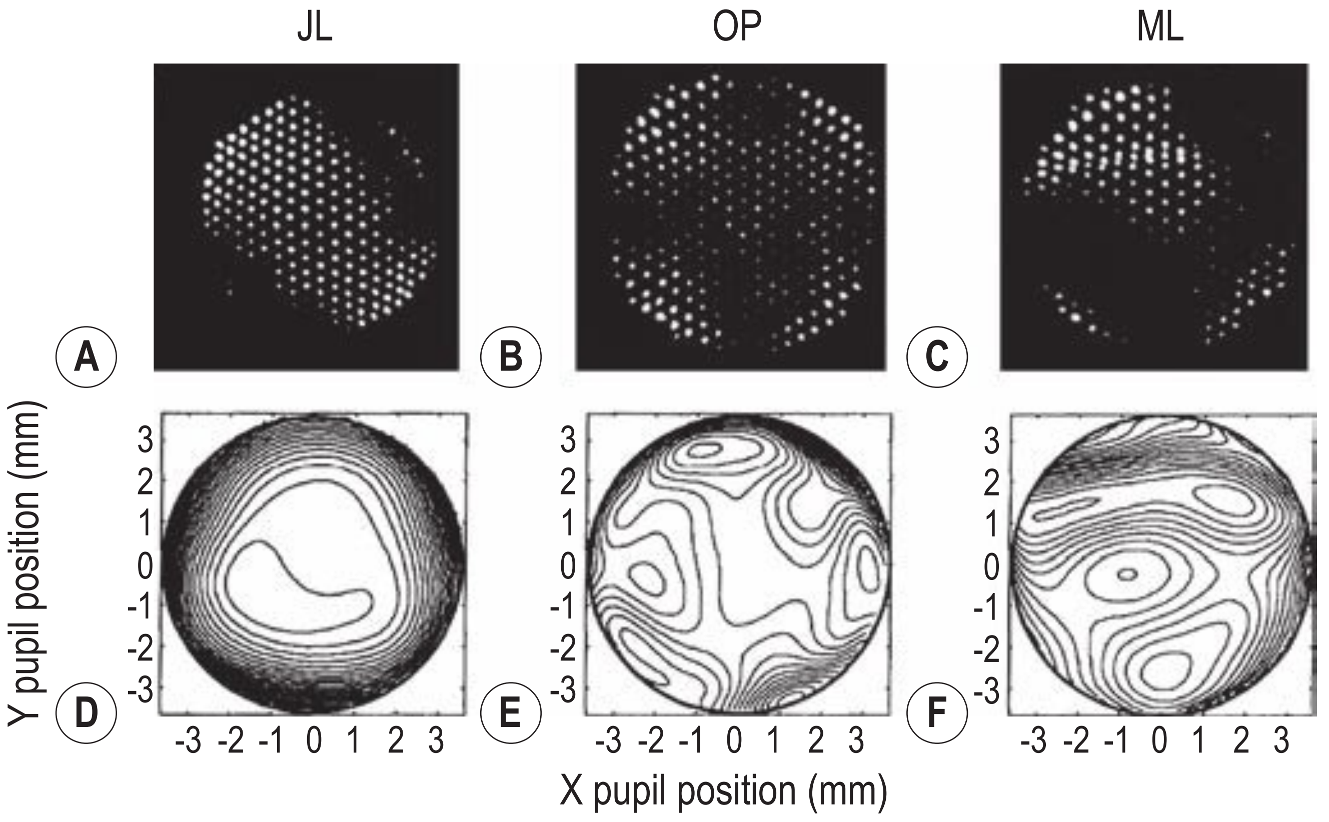


Fig. 3.11 (A–C) Wavefront sensor images on the visual axis for three eyes with a pupil diameter of 7.3 mm. An aberration-free eye would give a regular hexagonal lattice of points. (D–F) Corresponding derived wavefront aberration. Contours are at 0.15 µm intervals for subject OP and at 0.3 µm intervals for subjects JL and ML. The peak-to-valley wavefront error for a 7.3 mm pupil is about 7, 4 and 5 µm for JL, OP and ML, respectively. Note that for an aberration-free eye there would be a complete absence of contours. (Reproduced with permission from Liang, J. & Williams, D. R. (1997). Aberrations and retinal image quality of the human eye. J. Opt. Soc. Am. A, 14, 2873–2883.)

to factors such as accommodation fluctuations and tear-layer changes after a blink (Hofer et al., 2001; Cheng et al., 2004; Montés-Micó et al., 2004). There will also be variation in the measured wavefront errors owing to the limited reliability of any aberrometer. It can be seen, for example, that in Fig. 3.11 (A–C) the signal-to-noise of the Hartmann–Shack point images is poor in some cases; this may lead to errors in the estimates of the corresponding local slope and form of the wavefront.

Although the basic wavefront map gives a useful impression of the form and extent of the wavefront errors, it is helpful to be able to quantify this in some way. Various methods are available, but those that are the most popular at the present time are the total root mean square (RMS) wavefront error and the values of the Zernike coefficients for the wavefront error.

The basic method for obtaining RMS wavefront error for any diameter of pupil is easily understood. We divide the pupil into equal small areas, and sum the squared values of the wavefront error for each small area. This sum is then divided by the number of areas and the square root of this result gives the RMS wavefront error. It can be shown that, if the RMS aberration is less than a 14th of a wavelength (i.e. about 0.04 µm), there is negligible loss in retinal image quality in comparison with an eye whose performance is limited only by diffraction. Obviously for any eye the RMS error will vary with pupil diameter: in general, as the wavefront aberration tends to increase in the outer zones of the dilated pupil, the RMS aberration increases with pupil diameter.

Applegate et al. (2007) investigated axial RMS wavefront errors as a function of pupil diameter and age in a large sample of normal eyes that were corrected for spherical and cylindrical refractive error. Table 3.3 gives the means and standard deviations of their data for subjects aged 30–39 years.

It is interesting to note that the typical axial RMS wavefront error for a 3 mm pupil (see Table 3.3) is close to the limit at which the image differs negligibly from that from an aberration-free system (about 0.04 µm). The luminance at which this pupil diameter is found, a few hundred cd/m^2, corresponds to that found on cloudy days in the UK. Thus, in most eyes, wavefront aberration can play only a minor role in vision under daylight conditions.

To give some clinical insight into the image degradation caused by these levels of RMS wavefront aberration, we can roughly evaluate the blurring effect of the RMS aberration by equating it with those of an 'equivalent defocus' – that is, the spherical error in focus that produces the same magnitude of RMS aberration for the same pupil size. The equivalent defocus is given by:

$$\text{Equivalent defocus (D)} = 4.3^{1/2}\,[\text{RMS error}]/R^2$$

where the RMS aberration is measured in microns and the pupil diameter, R, in millimetres. Table 3.3 includes values for the equivalent defocus at each pupil diameter; except at the largest pupil diameter, the equivalent defocus is always less than 0.25 D. Although the assumption that equal RMS error produces equal degradation of vision is not completely justified (Applegate et al., 2003), it is evident that, in normal eyes, the impact of optical blur due to monochromatic aberration is modest under most photopic conditions. For comparison, the reliability of clinical refractive techniques is only around ±0.3 D (O'Leary, 1988; Bullimore et al., 1998).

The second common way of specifying aberrations is in terms of Zernike coefficients (Atchison, 2004; Charman, 2005). The idea here is that, as very different forms of wavefront can have the same total RMS error yet still produce somewhat different effects on vision, it is better to break the complex wavefront patterns of the type shown in Fig. 3.11 into a set of simpler 'building blocks'. Each 'block', mathematically described by a

TABLE 3.3 Variation in the Mean Axial Higher-order Monochromatic RMS Wavefront Error and its Standard Deviation in the Eyes of Subjects Aged 30–39 Years

Pupil Diameter (mm)	Typical Luminance Level (cd/m^2)	RMS Wavefront Error (µm)	Equivalent Defocus (D)
3	400	0.052 ± 0.022	0.16
4	70	0.102 ± 0.041	0.18
5	7	0.174 ± 0.062	0.19
6	0.1	0.289 ± 0.091	0.22
7	0.0005	0.513 ± 0.138	0.29

*Also given is the typical ambient luminance level at which the natural pupil diameters occur (taken from Fig. 3.8) and the equivalent defocus (see text).

(Data from Applegate, R. A., Donnelly, W. J., Marsack, J. D. et al. (2007). Three-dimensional relationship between higher-order root-mean-square wavefront error, pupil diameter, and aging. J. Opt. Soc. Am. A, 24, 578–587.)

Zernike polynomial, corresponds to a specific type of wavefront deformation: some of these are closely related to the traditional Seidel aberrations. The set of polynomials, named after their originator Fritz Zernike (1888–1966), has the advantage that the individual polynomials are mathematically independent of one another. The overall complex wavefront can then be specified in terms of the size of the contributions made by each of these constituent wavefront deformations: the size of the contribution that each makes is given by the value of the coefficient of the corresponding polynomial. In the recommended formulation in current use, each coefficient gives the RMS wavefront error (in microns) contributed by the particular Zernike mode (Atchison, 2004; Charman, 2005): the overall RMS wavefront error is given by the square root of the sum of the squares of the individual coefficients. The relative sizes of the different Zernike coefficients thus give detailed information on the relative importance of the different aberrational defects of any particular eye.

The Zernike polynomials can be expressed in terms of polar coordinates (ρ, θ) in the pupil, where $\rho = R/R_{max}$ is the relative radial coordinate, R_{max} being the maximum pupil radius, and θ is the azimuthal angle, defined in the same way as in the optometric notation, except that it can rise to 360°. Each polynomial, or wavefront building block, is defined by the highest power (n) to which ρ is raised (the radial order) and the multiple (m) for the angle θ (the angular frequency): $m = -2$, for example, means that θ appears as $\sin 2\theta$, while $m = +3$ means that it appears as $\cos 3\theta$. The polynomials and coefficients are, then, conveniently described as Z_n^m and C_n^m respectively. Fig. 3.12 shows the first few levels of the 'Zernike tree' formed by the different polynomials, the levels corresponding to successively greater powers of n.

The top two rows of the tree ($n = 0$ and $n = 1$) are of no significance for image quality: piston ($n = 0$) just corresponds to a longitudinal shift of the wavefront and tilts ($n = 1$) to small prismatic shifts in the image point. The second-order terms ($n = 2$) all depend upon the square of the radius in the pupil. This is, of course, a familiar feature of the sag formula and in fact Z_2^0 represents spherical defocus and the other terms astigmatism in crossed-cylinder form, with the principal meridians either at 45/135 (Z_2^{-2}) or 90/180 (Z_2^{2}). Thus, collectively, the second-order terms correspond to our familiar spherocylindrical defocus and can be compensated for by an appropriate contact lens or other type of correction. The higher-order (third and greater) polynomials represent the residual aberrations, which, in the past, it has not normally been possible to correct. Clinically these higher-order aberrations have often been described rather loosely by terms such as 'irregular astigmatism' and 'spherical aberration'. The third order includes vertical and horizontal primary coma and the fourth order primary spherical aberration.

What levels of Zernike aberrations are found on the visual axis in normal eyes? It must be remembered that, like the total RMS aberration, the values will tend to increase with pupil diameter, but a variety of studies involving large numbers of subjects give very similar results (Salmon and van de Pol, 2006). The study by Applegate et al. (2007) generated mean values for the magnitudes of different types of third- and fourth-order Zernike aberration for different pupil sizes and age (coefficients for still higher-order Zernike modes are usually much smaller). Table 3.4 gives their values for 30–39-year-old eyes. Note that, where appropriate, the coefficients for similar, but differently oriented, Zernike polynomials have been combined.

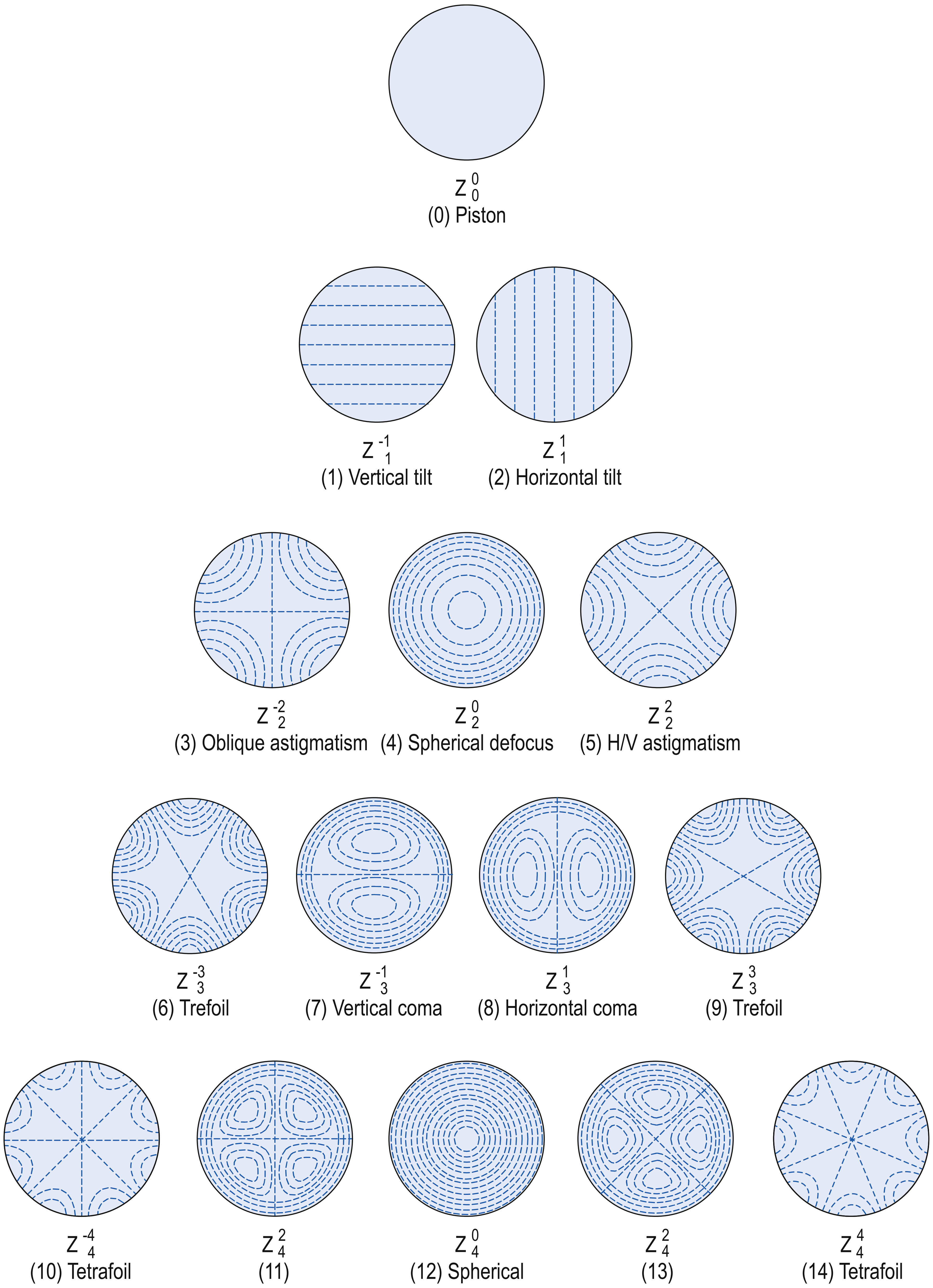
It is evident that, at the smaller 3 mm pupil size, third-order coma and trefoil aberrations tend to dominate over fourth-order aberrations, including spherical aberration, although spherical aberration becomes comparable to coma for the larger 6 mm pupil.

A somewhat different picture emerges if we average the signed coefficients, rather than considering the RMS values. Fig. 3.13 gives some typical data, in this case for a large sample (109) of normal eyes with a pupil diameter of 5.7 mm (Porter et al., 2001). What is striking is that almost all the modes have a mean close to zero, although individual eyes may have substantial aberration, as shown by the relatively large standard deviations. A notable exception is the $j = 12$, Z_4^0 spherical aberration mode, where the mean is positive and differs significantly from zero. Thus, the picture that emerges is that most eyes have a central tendency to be free of all higher-order aberration, except for spherical aberration, which shows a significant bias towards slight positive (undercorrected) values. The Zernike coefficients of normal individual eyes vary randomly about these mean values in a way that presumably depends upon the idiosyncratic surface tilts, decentrations and other asymmetries of the individual eye. The aberrations of eyes where pathology, such as keratoconus, is present may, however, be much larger.

Away from the visual axis, the major contribution to retinal image blur in the axially corrected eye is usually oblique astigmatism (Atchison, 2012a). The magnitude of the dioptric difference between the sagittal and tangential foci is similar in most eyes. Atchison and Smith (2000) suggest that this difference between the two power errors can be described by:

$$A(\theta) = 2.66 \times 10^{-3}\theta^2 - 2.09 \times 10^{-7}\theta^4$$

where θ degrees is the field angle with respect to the visual axis and the oblique astigmatism, $A(\theta)$, is in dioptres. Although the amount of astigmatism shows little variation, the relationship



Z_0^0
(0) Piston
Z_1^{-1}
(1) Vertical tilt
Z_1^1
(2) Horizontal tilt
Z_2^{-2}
(3) Oblique astigmatism
Z_2^0
(4) Spherical defocus
Z_2^2
(5) H/V astigmatism
Z_3^{-3}
(6) Trefoil
Z_3^{-1}
(7) Vertical coma
Z_3^1
(8) Horizontal coma
Z_3^3
(9) Trefoil
Z_4^{-4}
(10) Tetrafoil
Z_4^2
(11)
Z_4^0
(12) Spherical
Z_4^2
(13)
Z_4^4
(14) Tetrafoil

Fig. 3.12 The first five levels of the Zernike ‘pyramid’ or ‘tree’ showing the contour maps corresponding to the first 15 Zernike polynomials (up to the fourth order). The contour scale is arbitrary and, in the individual eye, will vary with the coefficient of each polynomial. Rows represent successive orders, n (i.e. the maximal power to which the normalized pupil radius is raised) and columns different azimuthal frequencies, m. Also shown (in brackets) are the index numbers, j, of the polynomials and some of the names used to describe them: polynomials (11) and (13) are often called secondary astigmatism. H/V astigmatism = horizontal/vertical astigmatism.

TABLE 3.4 Mean Absolute Levels RMS Wavefront Errors (WFE) of Different Types of Higher-order Zernike Aberration, and their Standard Deviations, for 30–39-year-old Subjects and Two Pupil Diameters

Aberration	Combination of Coefficients	RMS WFE (μm) for 3 mm Pupil Diameter	RMS WFE (μm) for 6 mm Pupil Diameter
Trefoil (j = 6 and 9)	$[(C_3^{-3})^2 + (C_3^3)^2]^{1/2}$	0.027 ± 0.017	0.139 ± 0.089
Coma (j = 7 and 8)	$[(C_3^{-1})^2 + (C_3^1)^2]^{1/2}$	0.031 ± 0.022	0.136 ± 0.087
Tetrafoil (j = 10 and 14)	$[(C_4^{-4})^2 + (C_4^4)^2]^{1/2}$	0.010 ± 0.004	0.056 ± 0.030
Secondary astigmatism (j = 11 and 13)	$[(C_4^{-2})^2 + (C_4^2)^2]^{1/2}$	0.015 ± 0.008	0.055 ± 0.027
Spherical aberration	C_4^0	0.014 ± 0.010	0.130 ± 0.090
Total higher-order RMS (j = 12)	$[\Sigma(C_n^m)^2]^{1/2}$	0.052 ± 0.022	0.289 ± 0.091

(Data from Applegate, R. A., Donnelly, W. J., Marsack, J. D., et al. (2007) Three-dimensional relationship between higher-order root-mean-square wavefront error, pupil diameter, and aging. J. Opt. Soc. Am. A, 24, 578–587.)

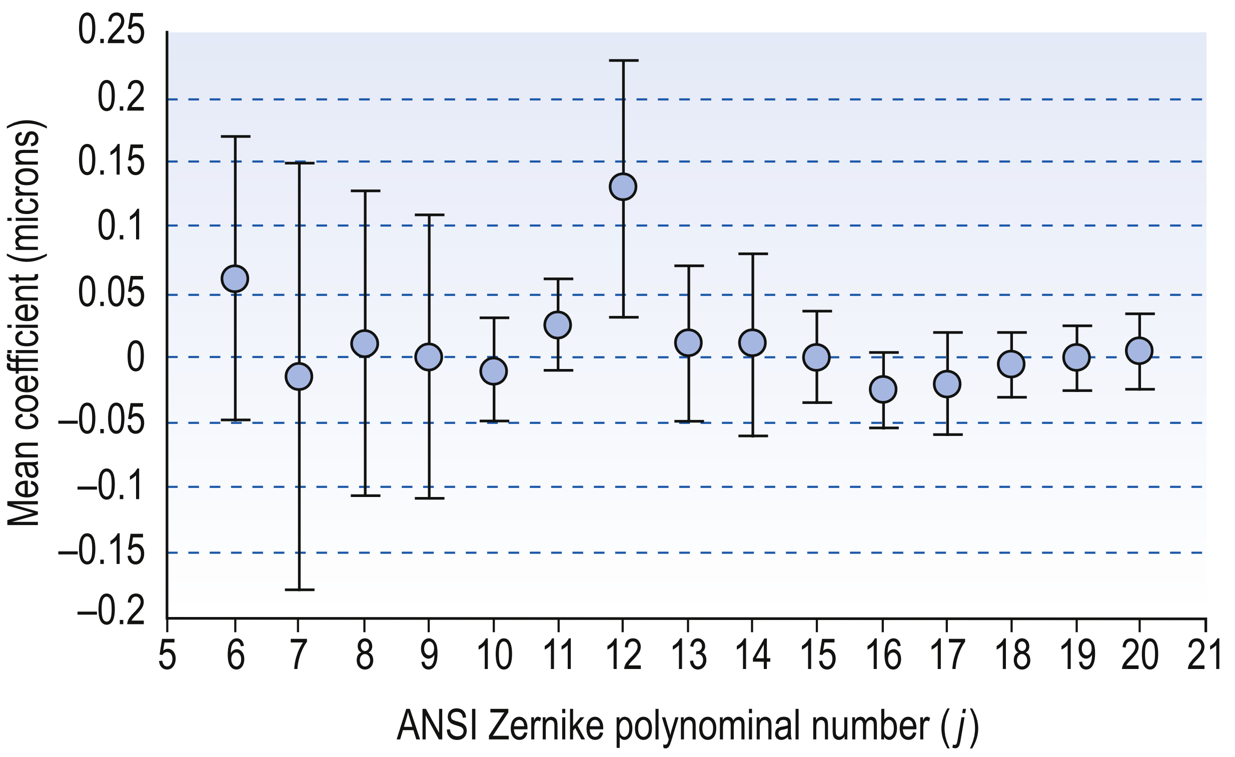


Fig. 3.13 Typical data for the means of the signed values of the Zernike coefficients of eyes at a pupil diameter of 5.7 mm: among the higher-order coefficients only j = 12 (C_4^0), spherical aberration, has a value that differs significantly from zero. ANSI = American National Standards Institute. (Adapted from Porter J., Guirao, A., Cox, I. G. & Williams, D. R. (2001). The human eye's monochromatic aberrations in a large population. J. Opt. Soc. Am. A, 18, 1793–1803.)

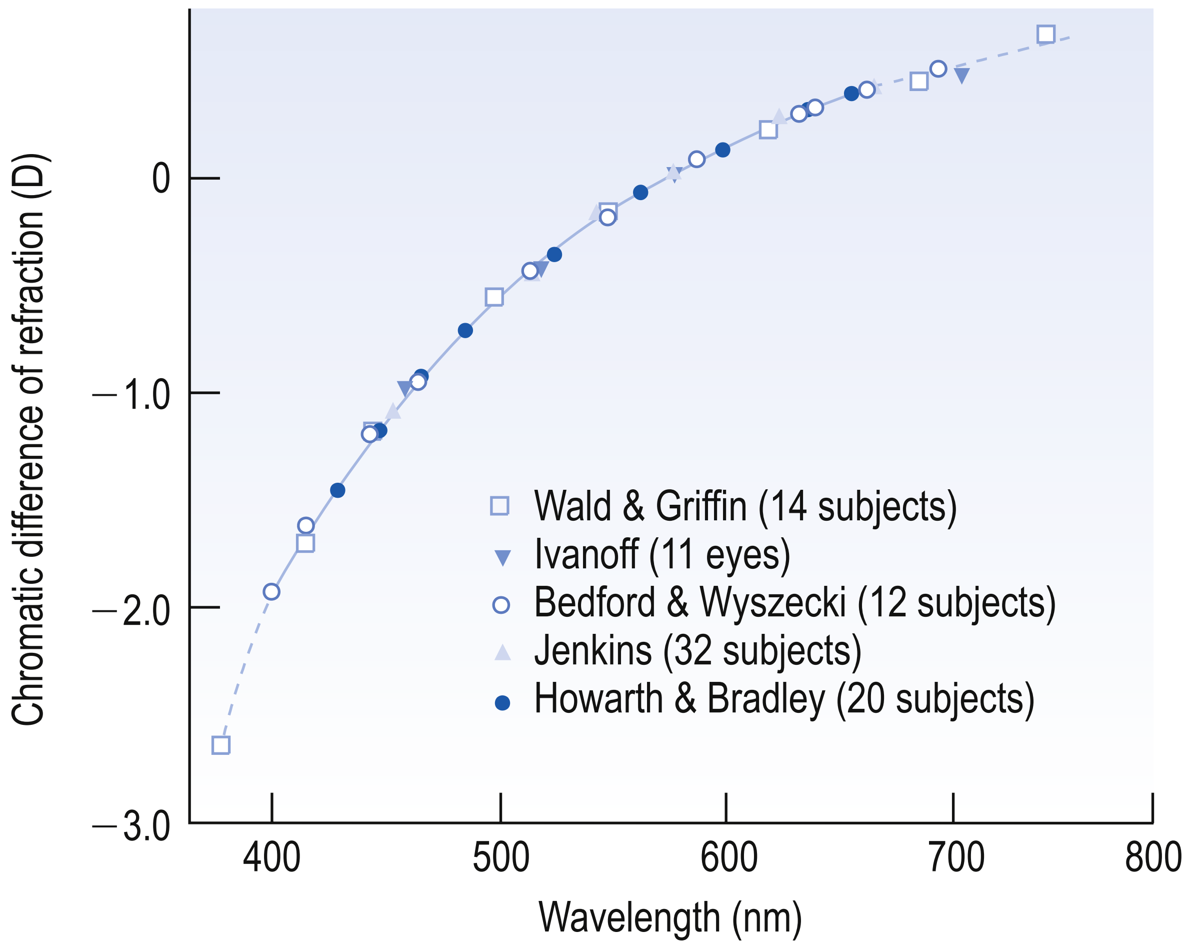


Fig. 3.14 The longitudinal chromatic aberration of the eye as found by different investigators. (Adapted from Charman, W. N. (1991). Optics of the human eye. In W. N. Charman (ed.) Vision and Visual Dysfunction. Vol. 1: Visual Optics and Instrumentation (pp. 1–26). London: Macmillan.)

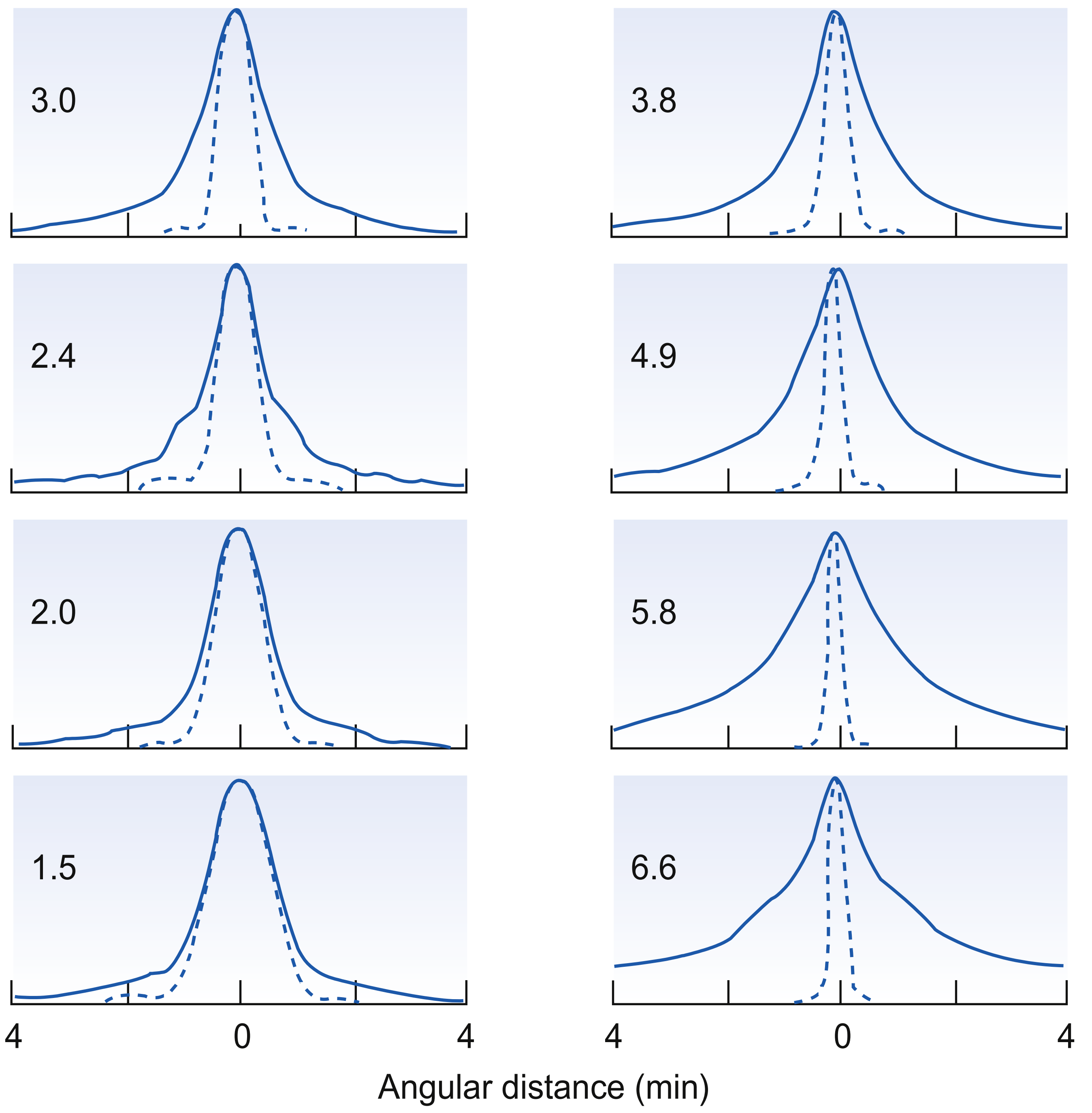


Fig. 3.15 White-light optical line spread functions for eyes with different pupil diameters (mm) at optimal focus. The solid line curves give the experimental measurements, and the dashed curves the theoretical result for a diffraction-limited system. (Adapted from Campbell, F. W. & Gubisch, R. W. (1966). Optical quality of the eye. J. Physiol. (London), 186, 558–578.)

between the two image surfaces and the retina varies across eyes and refractive groups. It has been speculated that those eyes where the mean sphere shows relative hyperopia in the periphery may be more susceptible to the development of myopia (Charman and Radhakrishnan, 2010; Smith, 2011; Flitcroft, 2012). For this reason there is ongoing interest in exploring the extent to which modifying the pattern of peripheral refraction, in particular by reducing relative peripheral hyperopia, by the wearing of suitably designed spectacles or contact lenses (Shen et al., 2010; Sankaridurg et al., 2011; Aller and Wildsoet, 2013), or by orthokeratology (Cho et al., 2005; Walline et al., 2009; Si et al., 2015), may reduce myopia progression in children. Results to date appear to be promising.

CHROMATIC ABERRATION

As the refractive indices of all the ocular media vary with wavelength, the eye suffers from both longitudinal and transverse chromatic aberration. At the fovea, the former is more important – the amount of aberration approximating to that which would occur if the eye media were all water. Unlike the monochromatic aberrations, longitudinal chromatic aberration varies very little between individuals and equals about 2.5 D across the visible spectrum (Fig. 3.14).

As the visual axis is usually displaced from the nominal optical axis of the eye by about 5°, some individually varying, transverse chromatic aberration is found at the fovea, typically amounting to about 0.8 min arc (Rynders et al., 1995); this further degrades foveal image quality.

OVERALL OPTICAL PERFORMANCE OF THE EYE IN WHITE LIGHT

Both monochromatic and chromatic aberration will degrade the in-focus retinal image in comparison with that which would be expected for an aberration-free eye with the same pupil size. Fig. 3.15 illustrates this for the case of the image of a fine line – that is, the line spread function.

The experimental results are compared with the calculated profiles for the aberration-free case (Campbell and Gubisch, 1966). With small pupils, aberration has only minor effects, but the performance deficit due to aberration steadily increases as the pupil diameter increases. It should, however, be borne in mind that under natural conditions large pupils are found only when field luminances are low and neural performance is poor. Thus diffraction-limited optical performance with large pupils would be of little value as the neural retina could not utilize the available information. Although monochromatic aberrations at constant pupil diameter tend to increase in later life, under natural conditions the pupil diameter is smaller, so that the quality of the retinal image changes very little (Applegate et al., 2007).

OCULAR DEPTH OF FOCUS

If the retinal image is gradually defocused, its quality will deteriorate owing to defocus blur. Nevertheless, there is a finite range of focus over which this blur causes no appreciable deterioration in visual performance. The precise value of the total depth of focus depends on how it is assessed (e.g. Atchison, 2012b), but Fig. 3.16 gives some representative photopic values from different studies. It can be seen that, for typical photopic pupils of about 4 mm diameter, visual performance will remain relatively unaffected provided that the spherical error of focus does not exceed about ±0.25 D.

CORRECTION OF HIGHER-ORDER OCULAR ABERRATION

Conventional corrections are designed to compensate for the spherocylindrical errors of the eye. As noted earlier, in wavefront terms these correspond to second-order wavefront aberrations. Would it be possible to improve visual performance further by also correcting the higher-order aberrations of the eye, as we can now easily measure these under clinical conditions? Until recently, the irregular and individual nature of the monochromatic wavefront aberrations of the eye made it impossible to correct them fully, although some reduction in the average spherical aberration could be achieved with appropriately aspheric contact lenses (see Chapters 6 and 13).

Longitudinal chromatic aberration can be corrected by a suitable achromatizing doublet lens, but the improvement in retinal image quality in white light is small and occurs mainly at intermediate spatial frequencies (Campbell and Gubisch, 1967); no improvement in conventional high-contrast, white-light visual acuity is normally detectable (Hartridge, 1947).

More recently, however, real progress has been made in correcting monochromatic aberration using either adaptive optics or liquid crystal phase plates (Liang et al., 1997; Vargas-Martin et al., 1998). Although all these corrections are, at present, feasible only in the laboratory, they do show that marked improvements in spatial vision can be achieved over the uncorrected eye, particularly if both monochromatic and chromatic aberrations are corrected; if only monochromatic aberrations are corrected, performance in white light improves only modestly (Yoon and Williams, 2001).

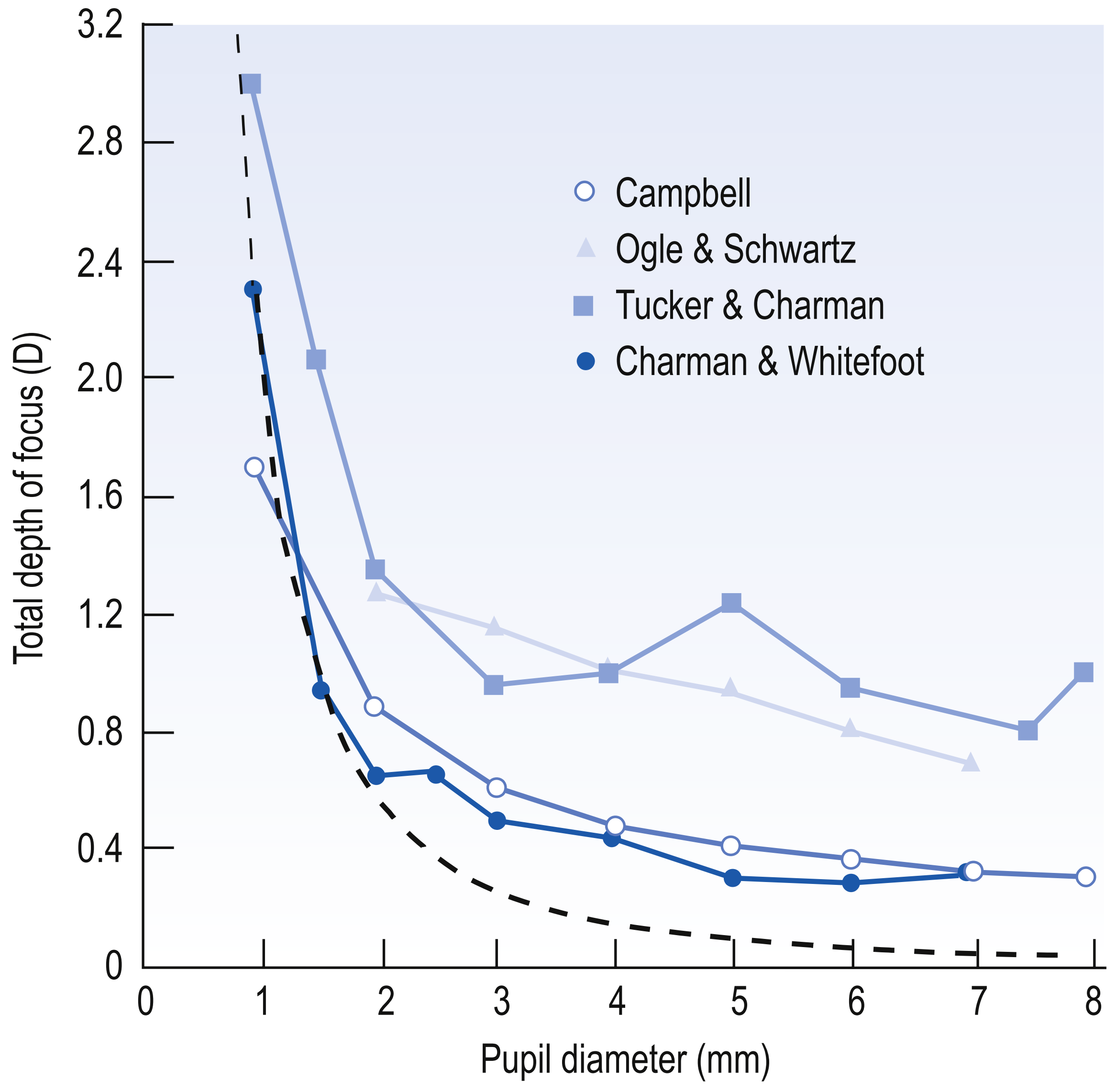


Fig. 3.16 Examples of experimental measurements of photopic, total monocular depth of focus/field as a function of pupil diameter (optimal focus lies midway through the total depth of focus). (Adapted from Charman, W. N. (1991). Optics of the human eye. In W. N. Charman (ed.) Vision and Visual Dysfunction. Vol. 1: Visual Optics and Instrumentation (pp. 1–26). London: Macmillan.)

Will it prove possible to correct axial ocular aberrations in everyday life? In theory, having measured the wave aberrations of the individual eye, the form of the cornea could be appropriately shaped, for example by a computer-controlled scanning spot excimer laser, to compensate for the aberrations. This has been the inspiration behind the development of many commercial aberrometers that, when coupled to suitably controlled excimer lasers, are used in wavefront-guided refractive surgery (Krueger et al., 2004). In practice, rather than eliminating monochromatic aberrations, this approach has so far only been able to ensure that postsurgery aberrations are comparable with normal levels, partly because of our limited knowledge of regression effects associated with corneal healing.

Alternatively a tight-fitting, customized, contact lens with minimal transverse and rotational movement might be engineered to play the same role (Klein and Barsky, 1995; Klein, 1998; Schweigerling and Snyder, 1998). The lenses would lack rotational symmetry and would be customized so that their local optical thickness varied in such a way as to compensate for the wavefront aberration of the individual eye. To improve optical performance in eyes with normal levels of aberration, any lens decentration should be less than about 0.5 mm and any rotation less than 10° (Bara et al., 2000; Guirao et al., 2001). However, such approaches would reduce only the monochromatic aberrations, which, in any case, change with the level of accommodation (Ivanoff, 1956; Lopez-Gil et al., 1998) and other factors (Charman and Chateau, 2003). The blur effects due to chromatic aberrations would remain uncorrected. Moreover, the worst monochromatic aberration occurs in the periphery of the dilated pupil, and pupil dilation occurs only when light levels are low and visual performance is largely limited by neural, rather than optical, factors. For these reasons, customized correction of aberration seems likely to be profitable only in the case of individuals whose monochromatic aberration is particularly high, as in keratoconus (Jinabhai et al., 2012). This problem is discussed further in Chapters 6 and 13.

Effectivity, Spectacle Magnification, Accommodation and Convergence Effects with Contact Lens and Spectacle Corrections

Many patients may wish to change from a spectacle to a contact lens correction, and vice versa. Although the corrections may be equally effective in producing in-focus retinal images in both eyes, they do have a number of slightly different secondary effects, most of which are associated with the fact that, whereas contact lenses are placed directly on the cornea, spectacle lenses are placed at a significant distance, typically 10–20 mm, in front of this surface. Corrections achieved by corneal ablation using excimer lasers, such as photorefractive keratectomy (PRK), laser in situ keratomileusis (LASIK) or other corneal surgical procedures, such as radial keratotomy or intrastromal rings, produce broadly similar effects to contact lenses, although their effective optical zones are usually smaller.

EFFECTIVITY

The role of the distance correction is to produce an intermediate image at the far point of the particular eye. Due to the non-zero vertex distance of any spectacle correction, this far point will lie at slightly different distances from the two types of correcting lens. Thus the spectacle and contact lens powers required to correct a particular eye will differ.

From Fig. 3.17A we can see that, using a reduced eye model, if the vertex distance is a (taken as positive) and the ocular refraction is K, giving a far point distance from the cornea $k = 1/K$, the second focal point of the correcting lens lies at a distance $a + k$.

Thus the power of the correcting lens (F_c) is:

$$F_c = 1/(a + k) = 1\,(a + 1/K) = K/(1 + aK)$$

For a contact lens, a will be zero so that the required value of F_c equals the ocular refraction in this simple model. This does not apply with a spectacle lens. The result is that a hypermetrope will require a higher-powered contact lens than a spectacle lens, the reverse occurring for a myope. The difference between the two correcting powers is plotted as a function of the spectacle correction for a vertex distance of 14 mm in Fig. 3.17B, from which it can be seen that the difference between the required powers of correction becomes significant (i.e. greater than 0.25 D) only when the magnitude of the ocular refraction exceeds about ±4 D. Appendix C provides a tabulation of ocular refraction values based on spectacle lens refractions for various vertex distances.

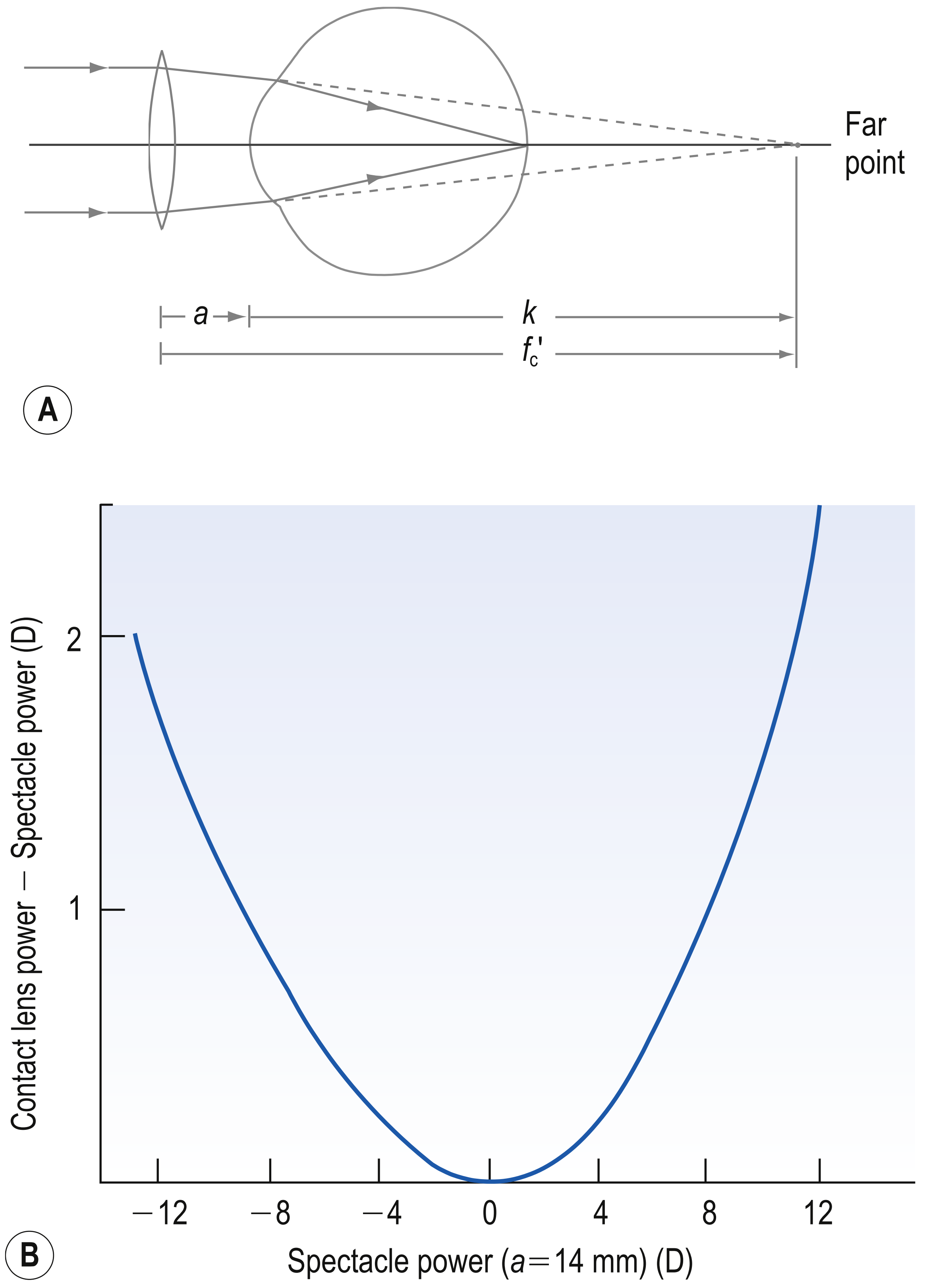


Fig. 3.17 (A) Geometry relating the far point of an ametropic eye (hypermetropic in the case shown) and the correcting lens. (B) Difference between the required powers of contact lens and spectacle corrections, as a function of the spectacle correction, assuming that the vertex distance of the spectacle lens is 14 mm.

SPECTACLE MAGNIFICATION

Spectacle magnification, as its name implies, describes the ratio of the image size in the corrected ametropic eye to that in the uncorrected eye. It is particularly significant in cases of anisometropia, where after correction the differential magnification of the two retinal images may give rise to symptoms of aniseikonia, and with cylindrical errors, where the different magnifications in the two principal meridians caused by the correction may lead the patient to complain of distorted images.

The retinal images of any object in the eyes of an uncorrected ametrope have a scale that is governed by the chief rays passing from the extremities of the object through the centres of the entrance and exit pupils of the eye. Each image point will, of course, be blurred (Fig. 3.18A). Although placing a contact lens on the cornea does not affect the course of the chief ray, and hence does not alter the size of the retinal image, this is not the case with a spectacle lens. A positive correction increases the angle that the chief ray makes with respect to the axis, whereas a negative correction reduces it.

Fig. 3.18B illustrates this effect for a positive, thin lens correction and a reduced eye with both entrance and exit pupils at the cornea. We define the spectacle magnification, SM, as the retinal image height in the corrected eye, h', divided by that in the uncorrected eye, h_0'. From the diagram it can be seen that, if all angles are assumed to be small:

$$SM = h'/h_0' = w'k'/w_0'k' = w'/w_0' = (w/n')/(w_0/n') = w/w_0$$

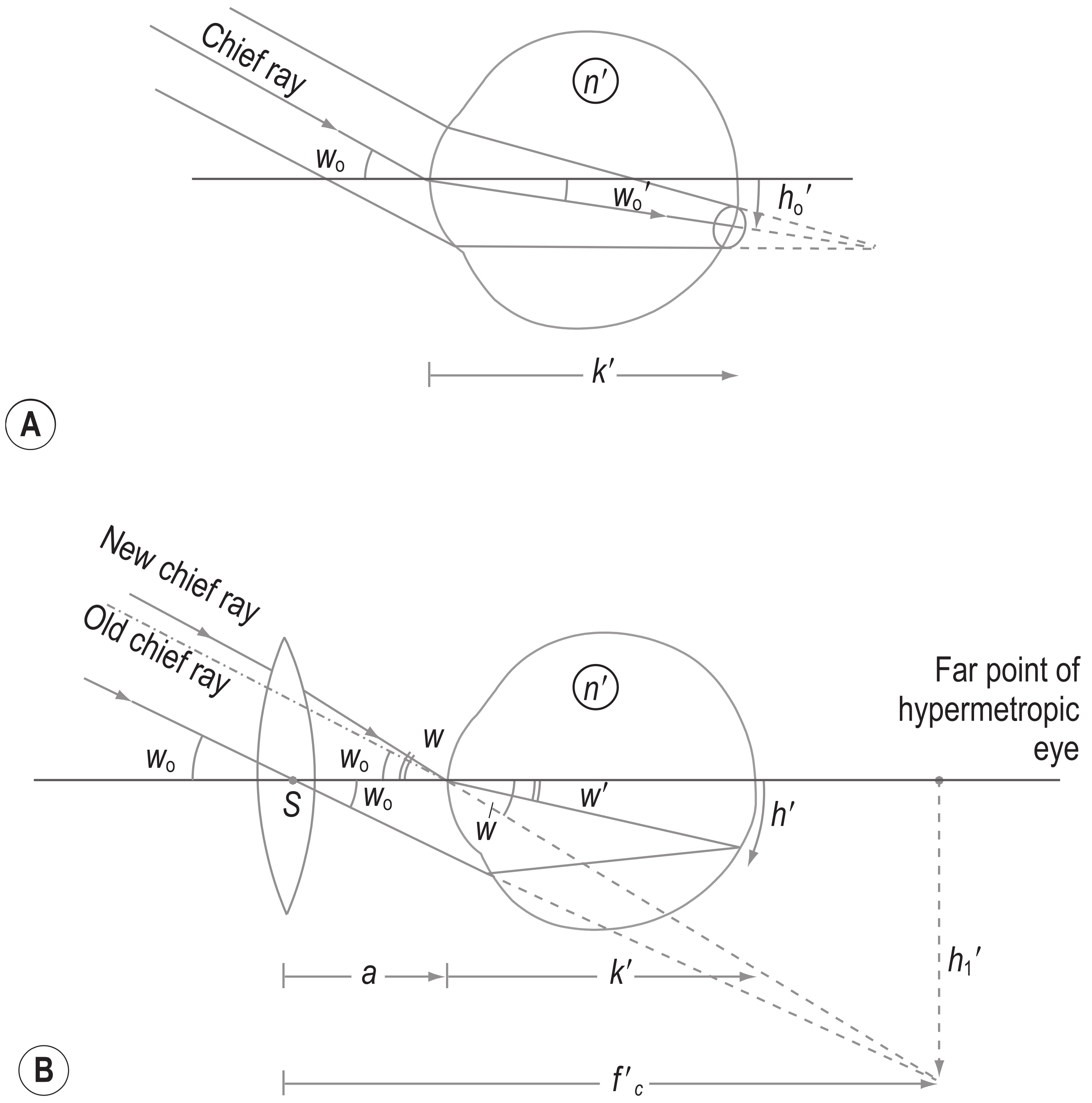


Fig. 3.18 (A) Ray geometry in the case of an uncorrected hypermetrope. (B) Effect of a correcting spectacle lens. Note that the angle that the incident chief ray makes with the axis is increased from w_0 without correction to w with correction. Correspondingly, the angle of the chief ray with the axis after refraction is increased from w_0' to w' after correction.

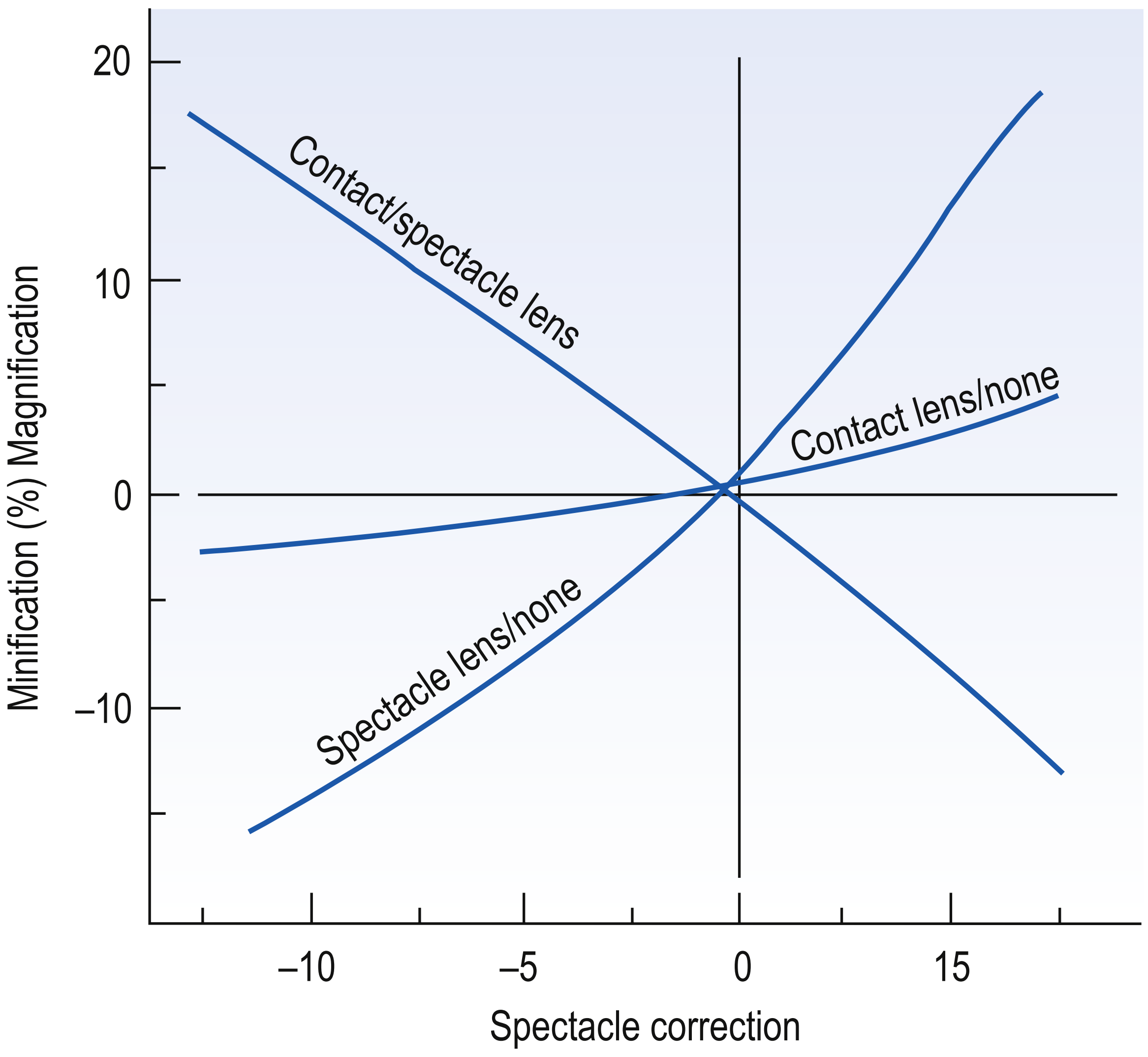


Fig. 3.19 Typical values for spectacle magnification obtained with spectacle lens and contact lens corrections. The ratio of the two spectacle magnifications is also shown. Effectivity has been allowed for, so that points on any vertical line refer to the same ametropia. (Adapted from Westheimer, G. (1962). The visual world of the new contact lens wearer. J. Am. Optom. Assoc., 34, 135–138.)

As the role of the correcting lens is to form an image of height h_1' at the far point, we thus have (Fig. 3.18B):

$$SM = [h_1'/(f_c' - a)]/[h_1'/f_c'] = 1/[1 - aF_c]$$

In this simple model, the spectacle magnification will be unity for contact lenses (vertex distance $a = 0$), less than unity for negative, myopic spectacle corrections and greater than 1 for positive corrections. Somewhat perversely, spectacle correction is often expressed as the percentage by which it differs from unity, so that a spectacle magnification of 1.05× would be described as '5% magnification'.

In practice we cannot strictly treat corrections as thin lenses and the entrance and exit pupils do not lie at the cornea. For practical purposes the pupils may be taken as being situated about 3 mm behind the cornea. Using a thick-lens extension of the arguments already used, it can then be shown that:

$$SM = [(1 - bF'_v)(1 - (t/n)F_1)]^{-1} \approx (1 + bF'_v)(1 + (t/n)F_1)$$

where b is the vertex distance measured from the back surface lens to the entrance pupil, and t, n, F_1 and F'_v are the lens thickness, refractive index, anterior surface power and back vertex power, respectively. It can be seen that the magnification is a function of both lens design and vertex distance. Fig. 3.19 shows typical values of spectacle magnification for both contact lens and spectacle corrections.

Note particularly that spectacle magnification is always close to unity for contact lenses, so that there are likely to be few magnification-related complaints from patients when moving directly from no correction to a contact lens correction or from one contact lens correction to another. Casual contact lens wearers who normally wear spectacle corrections may theoretically notice spatial distortion, although for myopes this is counterbalanced by the benefit of relatively larger retinal images, which may improve acuity. Spectacle magnification effects after corneal refractive surgery are similar to those with contact lenses (Applegate and Howland, 1993).

In addition to spectacle magnification as defined above, relative spectacle magnification (RSM) is sometimes discussed. This is the ratio of the retinal image size in the corrected ametropic eye to that in a specified emmetropic schematic eye. Theoretically it has the advantage of putting retinal image size on an absolute basis. However, in most clinical work it is the changes described by spectacle magnification that are of interest and RSM is of limited practical use.

As noted earlier, when anisometropes are corrected by spectacle lenses, marked differences in spectacle magnification may occur between the two eyes, which may result in symptoms of aniseikonia. It is obvious that these are much reduced in the case of contact lenses, which therefore minimize the possibility of aniseikonic symptoms (Winn et al., 1986). A closely related effect occurs when the anisometrope looks in different directions with the head in a fixed position. When ordinary spectacles are worn and the visual axes do not pass through the optical centres, prismatic effects are introduced, of magnitude given by Prentice's rule $P = cF_c$, where P is the induced prism power in prism dioptres, c the decentration in centimetres and F_c the lens power in dioptres. If the corrections are the same for both eyes, these prismatic effects cause no problems for the spectacle wearer. In anisometropia, however, the prismatic effects will be different for each eye. For example, in reading, the visual axes of a young anisometrope would normally intercept the lenses of the distance correction at some distance below the optical centres. Assuming this distance to be 8 mm and the corrections to be right eye (RE) −3.00 D, left eye (LE) −6.00 D, the prismatic effects would be RE 2.4Δ and LE 4.8Δ, respectively, both base-down. The difference in vertical prism power exceeds normal fusional abilities, so that, to avoid the problem, the spectacle-corrected anisometrope would have to execute head turns during reading rather than simply depress the visual axes. This problem is absent with well-centred contact lenses.

ACCOMMODATION DEMAND

Just as the position of the correcting lens affects the correcting power required and the spectacle magnification, so too does it influence the accommodation required to view a near object. The accommodation necessary with any particular correction can easily be calculated for any given object distance, lens position and correcting power by determining the difference between the vergence of the light striking the cornea when viewing a near object and that for a distant object. However, an adequate approximation for most purposes is that the accommodation demand (A, in dioptres) is given by:

$$A \approx -L(1 + 2aK)$$

where L is the object vergence (negative for real objects), a is the vertex distance and K is the ocular refraction. In this approximation, a is zero for a contact lens, so that we can see that for a myope (negative K) the accommodation demand is higher with contact lenses than with spectacle lenses, whereas the reverse is true for hypermetropes. If we consider an object at 33 cm ($L = -3$ D) and a spectacle vertex distance $a = 14$ mm, we find that the difference in demand with the two types of correction becomes significant (>0.25 D) when the magnitude of the refractive error, K, is larger than about 3 D. Thus, higher myopes approaching presbyopia might slightly delay the need for a reading addition by wearing spectacles, whereas

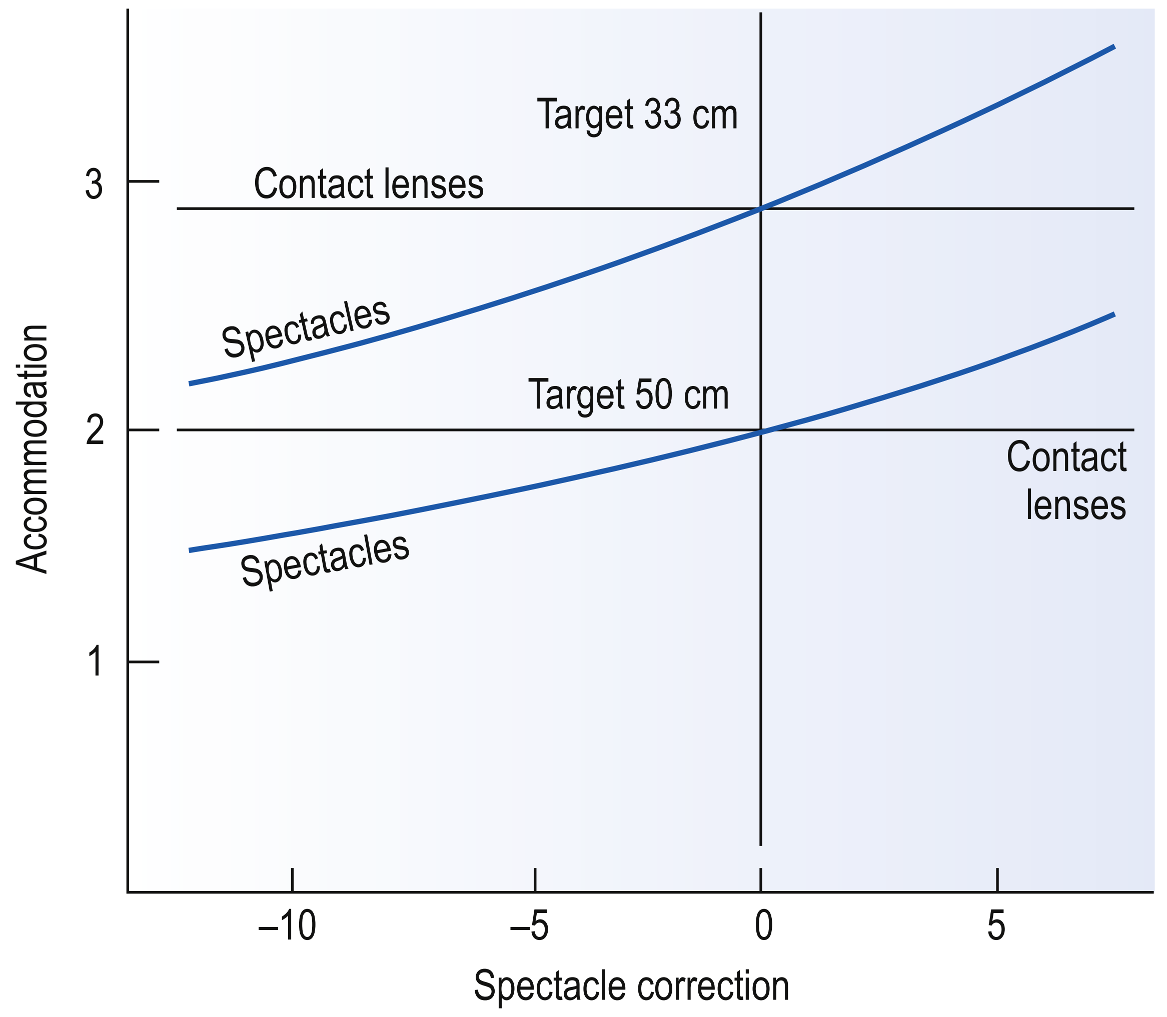


Fig. 3.20 Ocular accommodation required when a patient with the spectacle ametropia given on the abscissa views targets at either 0.50 or 0.33 m (vergence, $L = -2$ or -3 D) when corrected with either spectacles ($a = 14$ mm) or contact lenses. (Adapted from Westheimer, G. (1962). The visual world of the new contact lens wearer. J. Am. Optom. Assoc., 34, 135–138.)

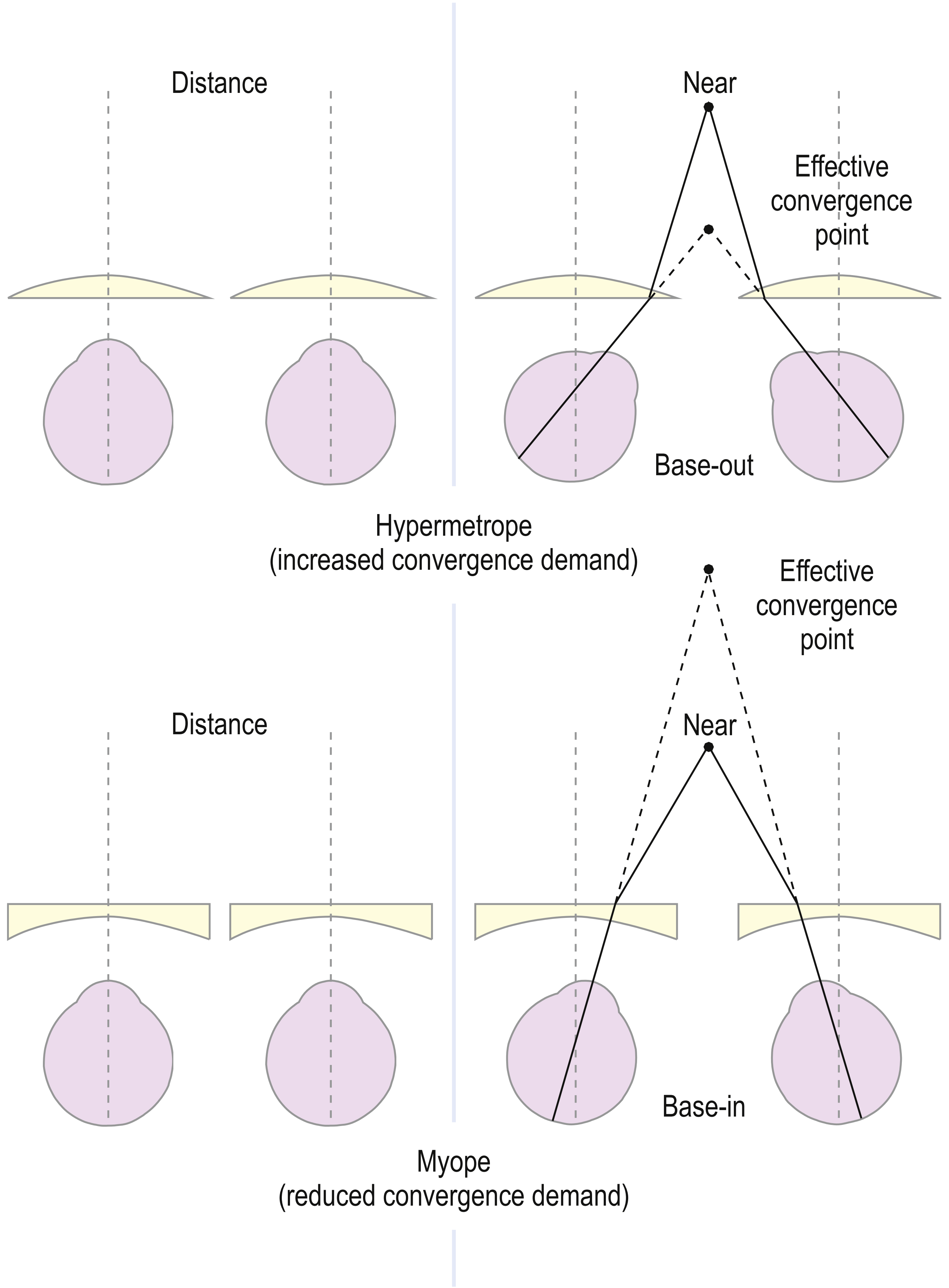


Fig. 3.21 Prismatic effects of distance spectacle corrections during near vision.

hypermetropes would find near vision easier with a contact lens correction.

Fig. 3.20 shows results from a slightly more refined model for the accommodation demand at two object distances.

CONVERGENCE DEMAND

Contact lenses move with the eyes, hence convergence demands when viewing near objects are identical to those applying in the uncorrected state. In contrast, myopes with a negative spectacle correction for distance observe near objects through base-in prisms, as they are no longer looking through the optical centres of their lenses (Fig. 3.21).

The base-in prismatic effects reduce the convergence requirement, compared with the naked eye or contact lens situation. Spectacle-corrected hypermetropes, however, experience a base-out effect at near, which increases the convergence demand. Allowing for a typical interpupillary distance of 65 mm and the centre of rotation of each eye being about 12 mm behind the cornea, application of Prentice's rule shows that, for an object distance of 33 cm, the convergence demand for each eye is reduced by about $0.25F_c$ prism dioptres for a negative spectacle correction and similarly increased for a positive correction. In most cases, then, the change in convergence demand is small compared with the fusion reserves. Since both accommodation and convergence demands are higher for myopes with contact lenses, and lower for hypermetropes, the accommodation–convergence links are minimally disturbed.

Other Optical Effects

There are certain additional phenomena related to prismatic effects of ophthalmic lenses that are not encountered by contact lens wearers. These phenomena, which are experienced by spectacle lens wearers, relate to the effective field of view in static gaze, the extent of eye movements required to maintain fixation and the appearance of the eyes as viewed by another person (or when looking in a mirror).

FIELDS OF VIEW AND FIXATION

With spectacle lenses, the prismatic effects associated with the lens peripheries result, when the eyes are stationary, in an annular zone of the visual field being invisible (a ring scotoma) with a positive correction, and being seen diplopically with a negative correction. Analogously, when the eye is rotated to view objects away from the axis of the correction, a larger eye movement, in comparison with the uncorrected eye, is required with a negative spectacle lens and a smaller one with a positive correction. This can be seen in Fig. 3.22.

If C is the centre of rotation of the eye, the effective field of view as seen through the spectacle lens is governed by the position of its image, C′, as formed by the correcting lens.

These fixation effects are absent with contact lens corrections, as the lenses follow the movements of the eyes from fixation to fixation. The periphery of the static field of view may, however, be slightly affected if the contact lens or its optical zone is small, and in the case of rigid lenses flare or glare may occur owing to discontinuities at the edge of the lens or optic zone affecting ray pencils from the periphery of the field. After laser refractive surgery, the optic zone diameter may be smaller than the dilated pupil, leading to complaints of haloes at night.

APPARENT SIZE OF THE EYES

A cosmetic disadvantage of spectacle lenses is that they alter the apparent size of the eyes of the wearer as seen by other people:

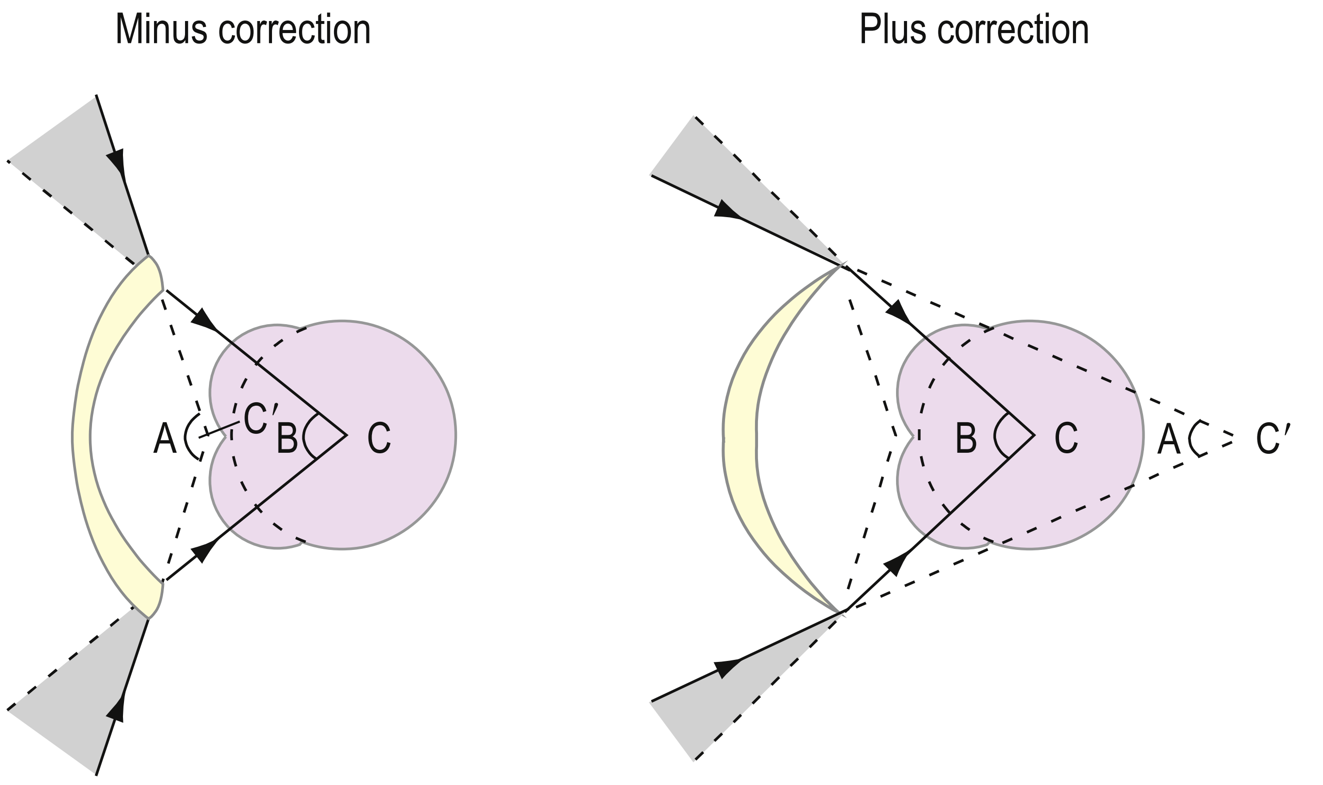


Fig. 3.22 Fields of view as seen through spectacle lens corrections. The centre of rotation of the eye is at C, and its image as seen through the spectacle lens is at C′. B is the apparent macular field of view and A the actual field.

the eyes appear larger with positive spectacle corrections and smaller with negative ones. Using a thin lens approximation, where the power of the correcting lens is F_c and the eye is at a distance l from the lens, it is easy to show that the paraxial magnification, M, of the anterior eye is given by:

$$M = 1/(1 + F_c l)$$

Because l is small (<0.02 m) this can be approximated by:

$$M = 1 - F_c l$$

Thus if l is −20 mm and F_c is −10 D, the eyes nominally appear to be only 80% of their true size. In fact, for the viewer the apparent size will vary depending upon the viewing direction, as conditions will not necessarily be paraxial. These magnification effects can be reduced by minimizing the vertex distance with high-powered spectacle corrections.

Clearly, with contact lenses this cosmetic disadvantage is absent.

Conclusion

It has been shown that, although various types of correction all produce sharp retinal images in the ametropic eye, the sizes of the associated retinal images will differ, as will the demands on accommodation and convergence. A particular advantage of contact lenses is that they produce little change in the retinal image size in comparison with the uncorrected eye.

Access the complete references list online at http://www.expertconsult.com.

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Soft Contact Lenses

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4

Soft Lens Materials

CAROLE MALDONADO-CODINA

Introduction

Soft contact lenses have had a massive impact on the global contact lens market since they became widely available in the early 1970s. Since their introduction, the number of soft contact lenses being prescribed around the world has steadily increased and it is mainly the sale of soft contact lenses that is responsible for an industry that is estimated to be worth around US$ 8 billion annually (Nichols, 2015). A recent survey has indicated that soft lenses currently make up about 87% of all contact lens refits worldwide (Morgan et al., 2016).

The saturation of the contact lens market with soft lenses has occurred primarily for two reasons. First, soft lenses provide wearers with what they see as the two most important requirements for successful contact lens wear – good vision and good comfort. The major obstacle as far as rigid lenses are concerned is generally accepted as being their lack of comfort and, in particular, their initial discomfort (Polse et al., 1999). Second, advances in manufacturing technology have directed the industry towards soft lenses and, still further, towards the concept of disposability.

Contact lens materials (both soft and rigid) are good examples of biomaterials. A biomaterial may be defined as a natural or synthetic material that is suitable for introduction into living tissue, especially as part of a medical device. The term encompasses a vast array of technologies, including tissue engineering, artificial organs, bioceramics, medical devices and implantable drug delivery systems. Contact lenses are classed as a medical device in most countries.

Very few of us are likely to get through life without having some kind of biomaterial introduced into our bodies. The most common examples in use today include dental fillings, contact lenses, intraocular lenses, heart valves and stents. This list in itself highlights just how diverse biomaterials must be in order to satisfy their very specific end application – for example, a contact lens material has very different properties to a material used for dental fillings.

If a biomaterial is to be successful in its application, it follows that it must also be biocompatible. Biocompatibility refers to the ability of a material to perform with an appropriate host response in a specific application. An 'appropriate host response' would include not having toxic or injurious effects on biological systems. Biomaterials manufactured for use as contact lenses must not only satisfy all these requirements for safe use within the eye, but additionally they must also have very specific characteristics such as being transparent (and remain so on-eye), be comfortable and be relatively cheap to manufacture.

This chapter reviews the building blocks, properties and characteristics of the materials that are used to manufacture soft contact lenses and provides some of the history of development of these materials. Most clinicians are familiar with the United States Adopted Name (USAN) of a particular lens material (e.g. etafilcon A or lotrafilcon A), but any further understanding of the material is often lacking. This chapter aims to give meaning and background to these USAN names in order to help the reader understand and differentiate between different soft lens materials.

Polymers

All contact lens materials may be classified as polymers. The word 'polymer' is derived from ancient Greek, meaning 'many parts'. Polymers are solid materials (as opposed to gases or liquids) that are made up of high-molecular-weight chains (i.e. long chains), which in turn are made up from small repeating units. These repeating units are called monomers. Polymers are macromolecules (giant molecules) made from thousands of atoms. The term 'polymer' is therefore an umbrella term for materials that include plastics (e.g. polymethyl methacrylate [PMMA], used in the manufacture of 'hard' rigid lenses), fibres (e.g. nylon), elastomers (i.e. rubbers such as silicone rubber) and the materials being discussed in this chapter – hydrogels.

The term 'hydrogel' is often used interchangeably with the term 'soft' when referring to contact lenses. Soft lenses are so named because they are made from water-swollen, cross-linked, hydrophilic polymers that are flexible and compliant. The term 'hydrophilic' is used to describe the fact that the networks from which these materials are made are 'water-loving'.

The widespread use of polymers in many areas of our everyday lives has become a common and accepted phenomenon – so much so that they have been referred to as the 'steel of the 21st century'. Polymers possess many properties that make them suitable for a wide range of applications, some of which are unique. These properties are in part due to the length of the molecules from which they are made. Additionally, polymers also derive their unique characteristics from the ability of certain atoms to join together to form stable covalent bonds.

Many polymers are composed of hydrocarbons (i.e. carbon [C] and hydrogen [H] alone) such as polyethylene and polystyrene. However, even though the basic make-up of many polymers is carbon and hydrogen, other elements can also be involved. Oxygen (O), nitrogen (N), chlorine (Cl), fluorine (F) and silicon (Si) are other elements commonly found in the molecular make-up of polymers. Many polymers have carbon backbones (these are considered organic polymers), but some can also have silicon or phosphorous backbones (these are considered inorganic polymers).

The kinds of atoms making up a polymer as well as their geometric arrangement give each polymer its chemical distinctiveness, and thus, its particular use and function. Polymers themselves may be completely natural (e.g. cellulose), partly natural (e.g. cellulose acetate) or completely synthetic (e.g.

PMMA). Most of the polymers used in the manufacture of soft contact lenses fall into this last category, i.e. they are man-made.

THE STRUCTURE OF POLYMERS

A polymer chain can be described by specifying the kind of repeating units present and their spatial arrangement. In this way, several broad categories of polymer can be described.

A homopolymer is one in which only one type of monomer is used, i.e. the units are chemically and stereochemically identical, with the exception of the end units. If the chain units are arranged in a linear sequence the polymer is referred to as a linear homopolymer. This is shown schematically in Fig. 4.1. Departures from this simple array lead to structures of increasing geometric complexity. A non-linear or branched structure is shown in Fig. 4.2.

The chemical differences between linear and branched polymers may be quite small, yet, because of the structural differences, the two molecules can have quite markedly different properties. A good example of these differences is found between low-density polyethylene (branched) and high-density polyethylene (linear). Low-density polyethylene is commonly used as a packaging film (e.g. cling film and for carrier bags), whereas high-density polyethylene is used for making pipes and durable plastic bottles because of its higher impact strength.

Non-linear and network structures can also be prepared from a collection of linear chains by covalently linking together chain units selected from different molecules. Such a system is said to be cross-linked. This is shown schematically in Fig. 4.3. Here, X represents the chemical species (the cross-linker) that covalently links together the A units from different molecular chains. When a sufficient number of units are intermolecularly cross-linked, an infinite network is formed. A cross-linker is an important ingredient in a soft contact lens monomer mix, which will be discussed later.

A copolymer is one in which more than one type of monomer is used. The properties of a copolymer depend not only on the chemical nature and amounts of the co-units, but also very markedly on how the units are distributed along the chain. For linear copolymers, three 'ideal' arrangements can be described. The first is an alternating copolymer, which is shown in Fig. 4.4. In this scenario, each monomer prefers to interact with the fellow monomer rather than itself.

At the opposite extreme is the ordered or block copolymer, where there is an overwhelming tendency for a unit to be succeeded by another of the same kind. Here, long sequences of one type of unit alternate with long sequences of the other kind (Fig. 4.5).

The third major classification is the random copolymer. Here, different units are randomly distributed along the chain (Fig. 4.6).

Departing from the restrictions of a linear array, branched copolymers, known as 'graft polymers', can also be prepared. The backbone of the molecule is composed of one type of unit, and the long side chains, or grafts, are made up of another. More sophisticated types of graft polymers have backbones made up of different repeating units and several distinctly chemically different side groups. This type of polymer is represented schematically in Fig. 4.7.

One final important classification is that of polymers into either amorphous or crystalline polymers (i.e. their macromolecular order) (Fig. 4.8). Crystalline polymers have a geometrically regular structure and are generally stiff, resistant to chemicals and tough. They have limited use as materials for contact lenses owing mainly to their poor optical qualities (i.e. they tend to be translucent or opaque). A good example of a semicrystalline polymer is polypropylene, which is often used to make the casts in the cast-moulded manufacturing process of contact lenses.

Amorphous polymers, on the other hand, do not have a regular structure. The polymer chains intermingle and are in

A—A—A—A—A—A—A—A—A—A

Fig. 4.1 Linear homopolymer.

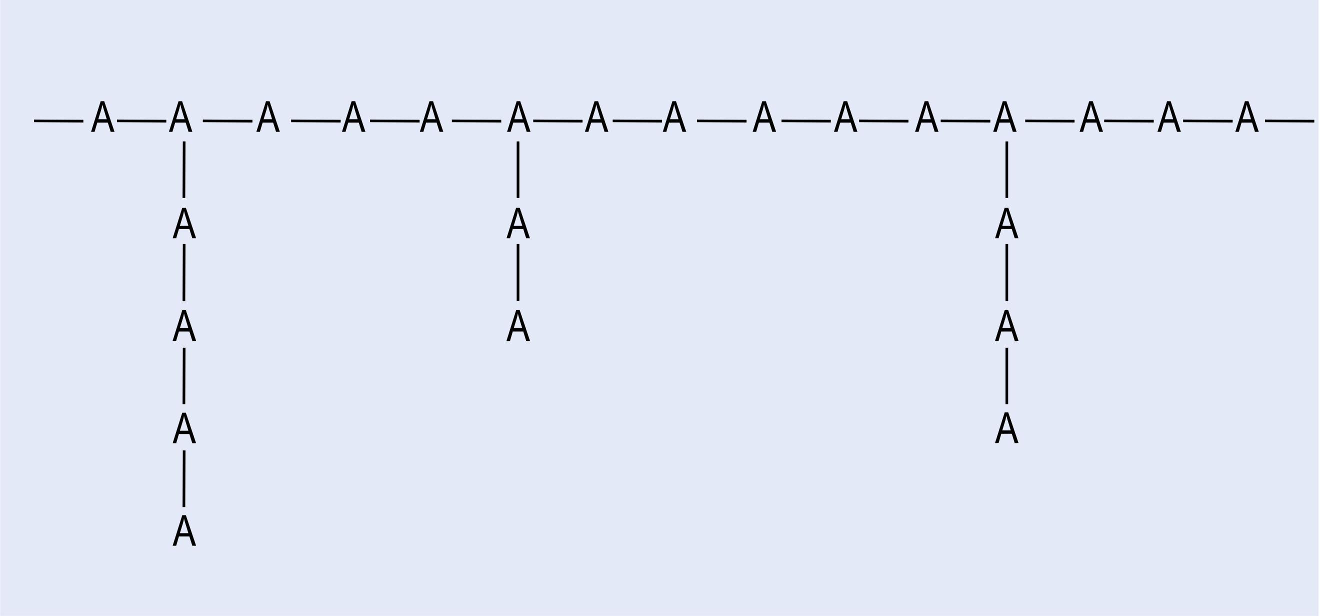


Fig. 4.2 Branched homopolymer.

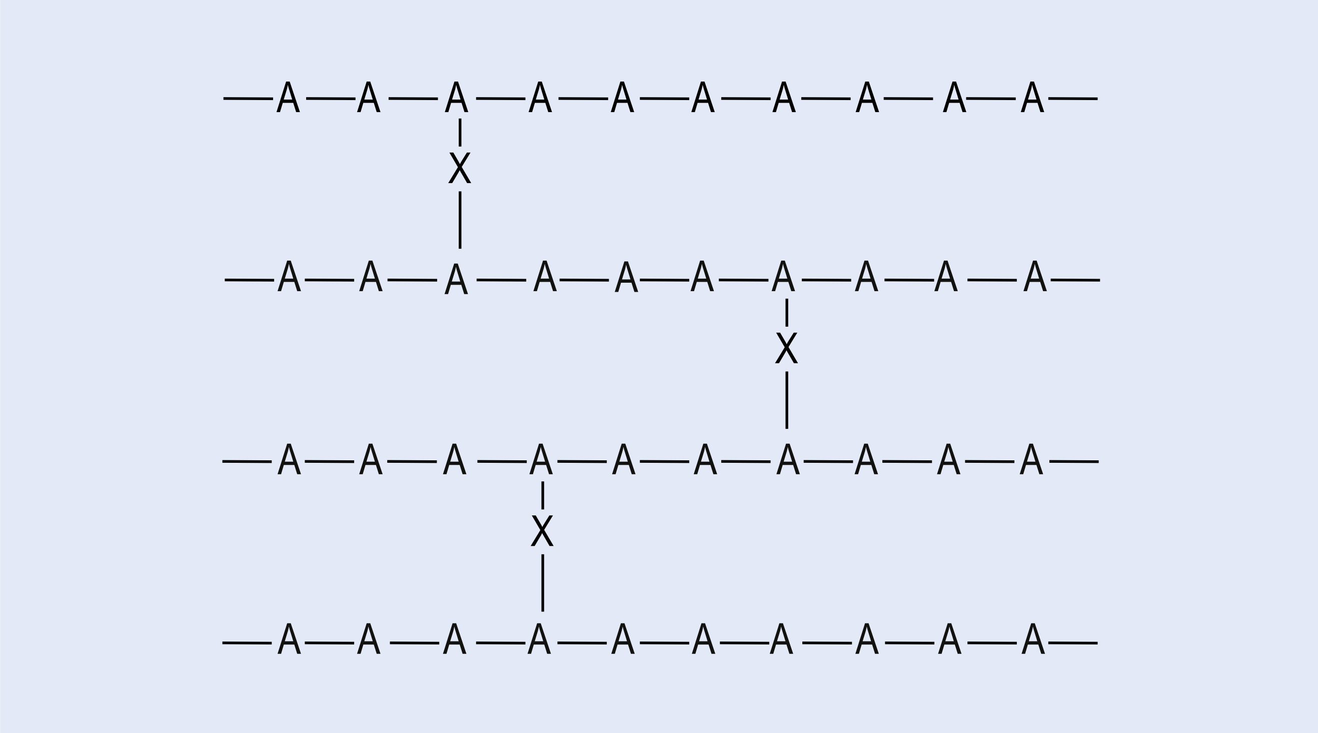


Fig. 4.3 Cross-linked system.

A—B—A—B—A—B—A—B—A—B—A

Fig. 4.4 Alternating copolymer.

A–A–A–A–A–A–A–A–B–B–B–B–B–B–B–A–A–A–A–A–A

Fig. 4.5 Block copolymer.

random positions (imagine a pile of spaghetti on a plate), which often allows these polymers to be transparent. Depending on their chain mobility, amorphous polymers can be classified as either 'plastic' or 'glassy' (Tighe, 1997).

POLYMERIZATION

The chemical reaction that monomers undergo in order to form long-chained polymers is known as polymerization. Broadly speaking, monomers can be chemically joined together in two ways: by step growth (condensation) or chain growth (addition) processes. Condensation polymers are produced by the reaction of monomeric units with each other, resulting in the elimination of a small molecule (e.g. water). However, hydrogels are generally formed through chain growth (addition) polymerization.

Before entering into the intricacies of polymerization it is important to establish that, in order to make a contact lens material, the following three basic 'ingredients' are required in the monomer 'mix': (1) the monomer(s), (2) a cross-linking agent and (3) an initiator. In some cases a solvent is also added to the monomer mix. A solvent is used when lenses are manufactured by 'wet casting,' where the solvent is gradually replaced with saline. If a solvent is not used, the manufacturing process is often referred to as a 'dry casting' (i.e. the contact lens is cast as a xerogel).

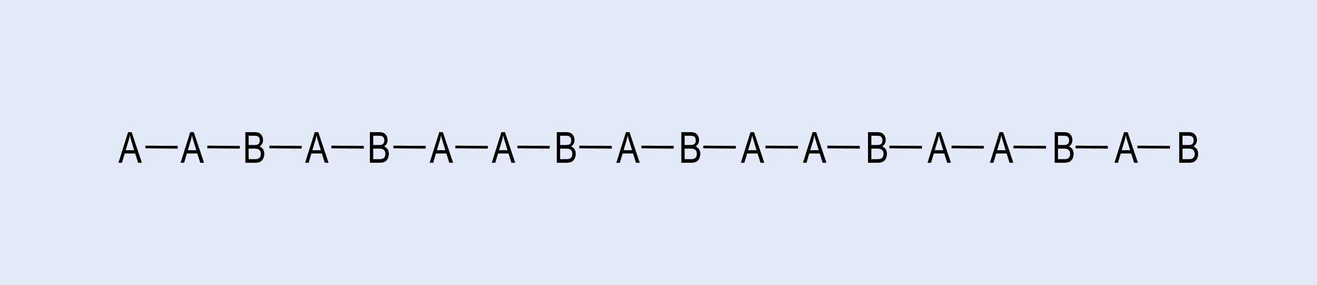


Fig. 4.6 Random copolymer.

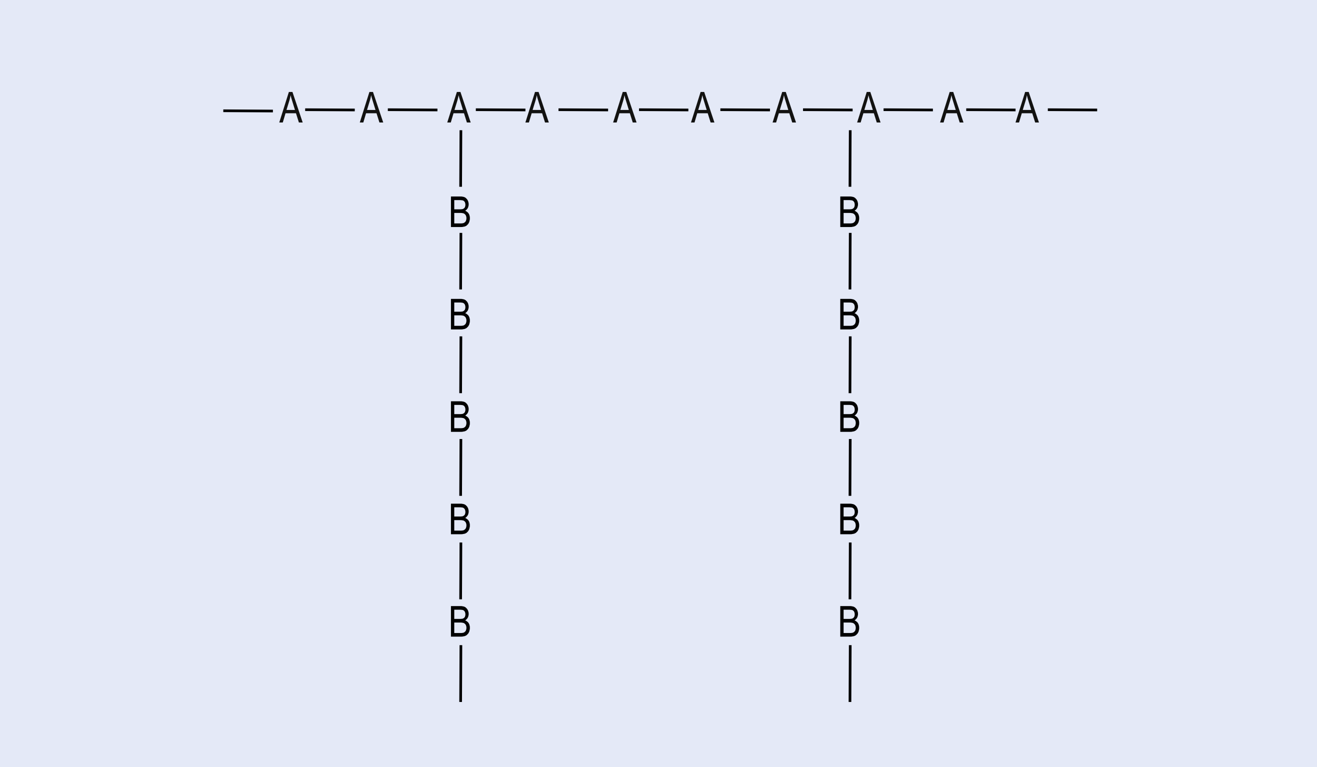


Fig. 4.7 Graft copolymer.

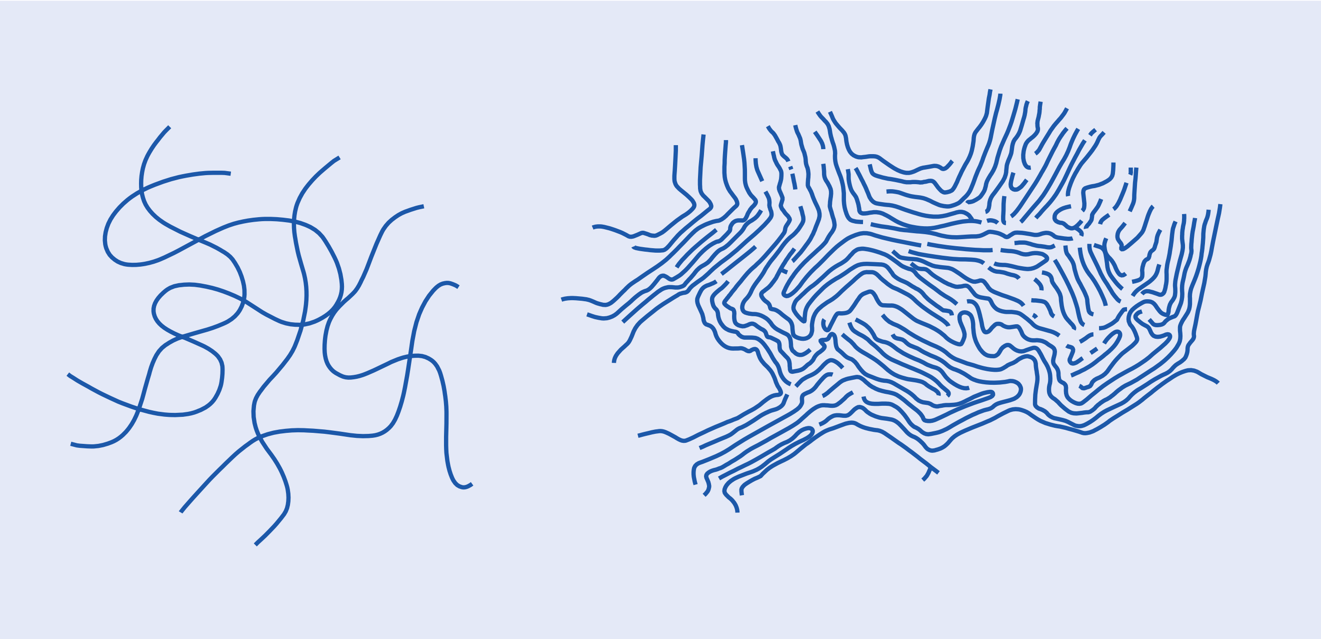


Fig. 4.8 Schematic representation of macromolecular order showing an amorphous polymer (left) and a crystalline polymer (right). (Redrawn from Kastl, P. R., Refojo, M. F. & Dabezies, O. H. (1984) Review of polymerization for the contact lens fitter. In O. H. Dabezies (Ed.) The CLAO Guide to Basic Science and Clinical Science. Orlando: Grune & Stratton Inc.)

Chain Polymerization

The monomers used in chain polymerization are unsaturated and are sometimes referred to as vinyl monomers. Essentially this means that the monomer has one or more carbon-to-carbon double bonds. During the polymerization process the monomer concentration decreases steadily with time, resulting in a reaction mixture that contains monomer, high-molar-mass polymer and a low concentration of growing chains. Chain polymerization is characterized by three distinct stages: initiation, propagation and termination.

Initiation. A hydrogel monomer mixture usually contains an initiator. This is a chemical whose role is to start off the polymerization process. Initiators readily fragment into free radicals (a highly chemically reactive atom, molecule or molecular fragment with a free or unpaired electron) when activated by heat or some other form of radiation (e.g. ultraviolet light).

The type of initiator used will depend on the manufacturing method. For example, a thermal initiator would usually be required in the manufacture of buttons or rods that will eventually form lathed lenses and a photo initiator would usually be required for spun-cast and cast-moulded lenses.

The fragmentation of the initiator is schematically represented by the following equation, where I represents the initiator molecule and $I^{\bullet}$ represents a free radical.

$$I - I \xrightarrow{\Delta} 2I^{\bullet}$$

The free radicals formed are then able to combine with the monomer (M), resulting in a free radical of the monomer (this is why the polymerization of hydrogels is sometimes referred to as free radical polymerization):

$$I^{\bullet} + M \rightarrow IM^{\bullet}$$

Propagation. The monomer radical, which is a transient compound, is now able to combine with another monomer unit, resulting in another new compound:

$$IM^{\bullet} + M \rightarrow IMM^{\bullet}$$

By the continuation of this process, the polymer chain is propagated. The resultant chain may consist of thousands of monomer units:

$$IM_n^{\bullet} + M \rightarrow IM^{\bullet}_{(n+1)}$$

Termination. Polymerization does not usually continue until all of the monomer has been used up because the free radicals involved are so reactive that they inevitably find a variety of ways of losing their reactivity. Polymerization can be terminated in two main ways. The first method is recombination. This occurs when two growing molecules containing free radicals meet, share their unpaired electrons and so form a stable covalent bond, thereby extinguishing their reactivity. The second method of termination is known as disproportionation. This occurs when two radicals interact via hydrogen abstraction, leading to the formation of two reaction products, one of which is saturated and one of which is unsaturated.

The conditions under which polymerization take place become important when one considers that soft contact lenses are currently made using three main methods of manufacture: lathing, spin casting and cast moulding; however, cast moulding is by far the most commonly used method. Lenses made by these different methods of manufacture will undergo very different polymerization conditions that are likely to have an effect on the resultant material. How a material is processed is likely to affect almost every aspect of a lens, from its clinical performance to its physical and chemical properties (Maldonado-Codina and Efron, 2004).

Properties of Hydrogel Materials

The ocular environment places significant demands on the performance of hydrogels as biomaterials. These materials must:

- maintain a stable, continuous tear film
- be permeable to oxygen in order to maintain normal corneal metabolism
- be permeable to ions in order to maintain on-eye movement
- be comfortable
- provide clear, stable vision
- be durable for the lifetime of the lens.

These essential properties are expanded upon below.

OPTICAL TRANSPARENCY

A hydrogel to be used as a contact lens material needs to be transparent in order to achieve maximal visual performance. The light transmittance of polymers includes the description of materials as being transparent, translucent or opaque. Transparent polymers are those that you can see through, translucent polymers are those that you cannot see through but allow light to pass through, and opaque polymers are those that you can neither see through nor allow light to pass through. Usually the optical clarity of contact lens materials is expressed as the percentage of transmission of the visible electromagnetic spectrum. Hydrogels that are useful as contact lens materials transmit over 90% of light in the visible part of the spectrum.

When a hydrogel loses its transparency it is likely to be due to microphase separation of water. This is due to regions of differing refractive index being formed within the gel. Hydrogels that show this type of behaviour (typically synthesized by making copolymers with large blocks or segments of hydrophobic and hydrophilic monomers rather than randomly dispersing them) do have advantages in terms of enhanced strength and permeability performance.

If the phase separation is limited (e.g. the phase size is shorter than the wavelength of light), transparent materials can still be obtained. Some hydrogels are known to lose their transparency when heated and this is an important consideration as there is an increase in temperature from lens packaging to eye and, additionally, some patients still thermally disinfect their lenses, although this practice is seldom employed today.

Trying to combine hydrophilic hydrogel monomers and hydrophobic silicone-based monomers into transparent hydrogels has been a major technical difficulty in the development of successful silicone hydrogel materials. Tighe (2004) likens this technical challenge to trying to mix oil with water.

MECHANICAL PROPERTIES

The mechanical properties of hydrogel contact lenses are fundamentally important because they are directly related to factors such as the comfort, visual performance, fitting characteristics, physiological impact, durability and handleability of the lenses.

In the hydrated state most hydrogels are soft and flexible. When they are allowed to dehydrate they become hard and brittle. Lower-water-content polymers tend to become more hard and brittle than higher-water-content materials. Hydrogels take up water because they are hydrophilic; that is, hydrogels swell in water (as well as many other liquids), which causes them to become soft with elastic properties (the water acts as a plasticizer).

Unlike perfectly elastic materials, which deform under stress but return to their original size and shape when the stress is released, hydrogels are viscoelastic. This means that they deform time-dependently when a stress is applied to them and recover time-dependently when the stress is removed. Theoretically, this can result in permanent deformation of the material.

One of the main difficulties in characterizing the mechanical properties of a contact lens is that there is no single property measurement that will accurately reflect its 'in-use' situation. Traditional material mechanical testing involves applying a deforming force (the 'stress') to a sample and observing the way that the sample responds (the 'strain').

Stress can be compression, tensile or shear. Compression is a stress that acts to shorten an object. Tension is a stress that acts to lengthen an object. Shear is a stress that acts parallel to a surface. Strain is defined as the amount of deformation an object undergoes compared with its original size and shape. When a tensile stress is applied to a material, the stress gradually builds up until the specimen breaks (fractures).

A generalized stress–strain curve is shown in Fig. 4.9 and provides several mechanical characteristics of the material under test. The strength of a material is defined as the force per cross-sectional unit area required to cause failure when the

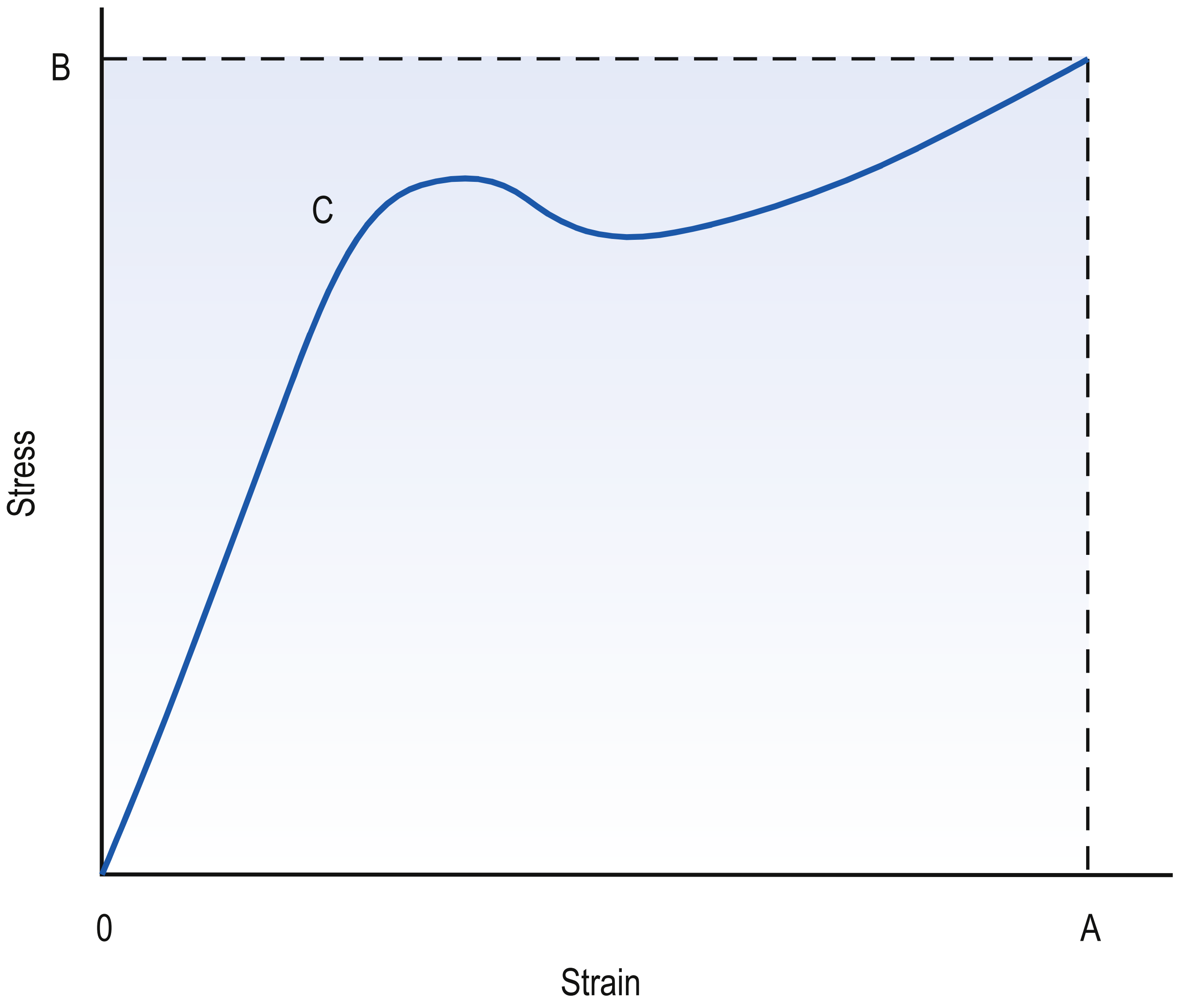


Fig. 4.9 Typical tensile stress–strain curve for a theoretical material. Point A on the graph represents the elongation at break, point B represents the ultimate strength and point C represents the yield point of the material. A typical soft lens hydrogel does not demonstrate a yield; instead, it would break at point C on the graph.

sample is subjected to a particular type of stress. Some materials will go through a yield point, which is defined as the stress at which a material begins to deform plastically. Contact lens hydrogels typically do not demonstrate a yield point. Young's modulus (E), or the elastic modulus, is determined by the initial slope of the stress–strain curve and is, therefore, a constant (i.e. it is the stress divided by the strain). Young's modulus and the thickness of the material (t) are related together in determining the stiffness of a lens. Just as Dk / t indicates the relative transmissibility of different lenses, so the stiffness factor multiplied by the thickness (E × t) indicates the relative resistance to deformation of the lens.

It is important to note that several different moduli can be measured, but Young's modulus is the one that is most commonly referred to in association with contact lenses. The elongation at break of the material, also referred to as the strain, is the fraction of its original length that a material stretches when placed under a load. It is a measure of how much the material can deform before breakage. Strain is dimensionless (i.e. it has no units attached to it).

A point of potential confusion in the literature is the lack of standardization of the units used for measuring stress. Stress is defined as force per unit area. The Système Internationale (SI) unit of stress is N/m^2 (newtons per square metre). One newton is the force required to give a mass of 1 kg an acceleration of $1\ m\,s^{-2}$. A newton spread out over a square metre is a pretty feeble force, so MN/m^2 (mega newtons per square metre or $10^6\ N/m^2$) is a more useful unit.

The pascal is also seen in the literature with reference to stress. The pascal is actually the SI unit of pressure. The units of pressure are defined in the same way as those for stress: force / unit area. One pascal is the pressure generated by a force of 1 N acting on an area of $1\ m^2$ ($1\ Pa = 1\ N/m^2$). Mega newtons / m^2 and mega pascals, therefore, have numerically equal values.

In US customary units, stress is expressed in pounds-force per square inch (psi). The conversion factor is as follows:

$$1\ MPa = 145.0377\ psi$$

The strength of a hydrogel gives some indication of the behaviour of the material during handling, whilst the modulus indicates the extent to which the eyelid will deform it and has an impact on the fitting characteristics of the lens in addition to its comfort. Rigid lens materials have a relatively high modulus (in the region of 10^3 MPa), whereas soft lens materials have a much lower value when in the hydrated state (in the region of 0.2–1.5 MPa).

Since the introduction of silicone hydrogels in the late 1990s there has been renewed interest in the concept of 'modulus' as an important soft lens physical property. These lenses (particularly the early 'stiffer' first-generation silicone hydrogel lenses) generally have a higher tensile modulus than do hydrogels. The higher moduli of these materials have certain clinical implications, which are discussed in more detail in the silicone hydrogel materials section of this chapter.

The generally poor mechanical strength (including tear strength) of soft lenses is arguably the main reason why they have relatively short lifetimes. This problem has been somewhat overcome by the introduction of disposable lenses, which essentially means that the majority of soft lenses no longer need to last more than a day, 2 weeks or a month, depending on their intended replacement schedule.

Several factors can affect the mechanical properties of a hydrogel material and these can be broadly divided into: (1) material composition factors and (2) polymer-processing factors. Examples of material composition factors include changing the comonomers used in the hydrogel preparation. If the hydrogel is not a homopolymer, then increasing the relative amount of physically stronger component(s) will lead to an increase in the final mechanical strength of the material. This may have the effect of altering the mechanical strength by increasing the stiffness of the backbone polymer, for example by replacing acrylates with methacrylates, or it may alter the hydrophilicity of the polymer by replacing hydroxyethyl methacrylate (HEMA) with methacrylic acid (MAA). In general, as the equilibrium water content (EWC) of a hydrogel increases, its modulus decreases.

Another important material composition factor is that the mechanical properties of a hydrogel are dependent on the cross-link density in the system. Cross-links act as anchors or physical links and prevent the polymer chains from slipping past each other. In general, the strength of a hydrogel increases with increasing cross-link density, particularly when in the swollen state, where physical entanglements are low.

Cross-link density can be increased by the addition of larger amounts of cross-linking agent. Although increasing the cross-link density within a hydrogel network is beneficial in relation to its mechanical properties, it must also be considered that changes to other properties of the polymer will occur. The swelling capacity of the hydrogel is likely to be reduced with increasing cross-link density, and hence, its oxygen permeability will also be reduced, which is undesirable in a contact lens material. A balance of all the properties of a polymer is critical to its end application.

Polymer-processing factors that can affect the mechanical properties of a hydrogel essentially refer to the fact that hydrogel materials are highly sensitive to the processing and fabrication conditions to which they are subjected. Lenses made by different methods of manufacture will undergo very different material processing, particularly polymerization. These different material-processing steps may have an effect on the mechanical properties of the resultant lens. For example, lathed lenses are formed from solid buttons of dehydrated material and these buttons are usually bulk-polymerized over relatively long periods compared with a cast-moulded lens. Thermal initiators are often used in button production, which have low activation energies, allowing water baths or ovens to be set to relatively low temperatures. This type of polymerization is likely to lead to a polymer structure consisting of longer chains (higher molecular weights) and therefore more chains.

In the cast-moulding process a small amount of monomer is placed between two casts to form the lens directly. The polymerization process is typically very fast, which is one of the reasons why this is the method of choice for bulk (disposable) lens manufacture. Rapid polymerization times are likely to produce shorter chains, more chain ends and less efficient cross-links.

SURFACE PROPERTIES

The surface characteristics of a hydrogel lens will directly affect its interactions with the tear film and consequently its biocompatibility in the ocular environment. 'Wettability' is used to describe the tendency for a liquid to spread on to a solid surface, and in vivo wettability in a contact lens context implies the ability of the tear film to spread and maintain itself over a contact lens surface. In vivo wettability is a key measure of clinical performance because the success of any contact lens is considered to be related to its ability to support a stable tear layer in the eye. General clinical consensus is that failure to meet this requirement is likely to result in a lens that is uncomfortable, has reduced visual performance and forms deposits rapidly. The quality of the pre-lens tear film will also have an effect on the friction between the eyelid and the lens surface. This in turn is thought to be important in the aetiology of physiological responses such as contact-lens-related papillary conjunctivitis (CLPC) and lid wiper epitheliopathy (LWE). The issue of wettability has received considerable attention since the introduction of silicone hydrogel materials at the turn of the century, in view of the potentially poor wettability of lenses manufactured from this material.

In vivo wettability is generally assessed with a range of relatively crude clinical tests that have been used for several decades. These include tear film break-up time (with or without the presence of fluorescein), interferometry and various techniques based around specular reflection. Unfortunately, these methods frequently fail to differentiate adequately between lens surface types, even when relatively different lens surfaces are evaluated.

On the other hand, laboratory measures of wettability are well established and are often better at differentiating lens surfaces. Wettability in relation to contact lenses has traditionally been assessed in vitro using contact angle analysis. When a drop of liquid is placed on a solid surface, an angle is formed at the solid–liquid–air interface (Fig. 4.10). This angle is referred to as the contact angle.

Contact angles can be equilibrium, advancing or receding. The advancing contact angle is the angle formed when a liquid is advanced over an unwetted surface. The receding contact angle is the angle formed when a liquid is withdrawn over a previously wetted surface. There is usually a difference between the advancing and receding contact angles (the advancing angle is usually the larger one) for hydrogel materials and this difference is referred to as the 'hysteresis'. Essentially, the smaller the contact angle, the better the liquid spreads over the solid surface and the more wettable is the solid surface. It is, however, important to bear in mind that the relationship between these laboratory measurements and the clinical performance of the lenses is not fully understood.

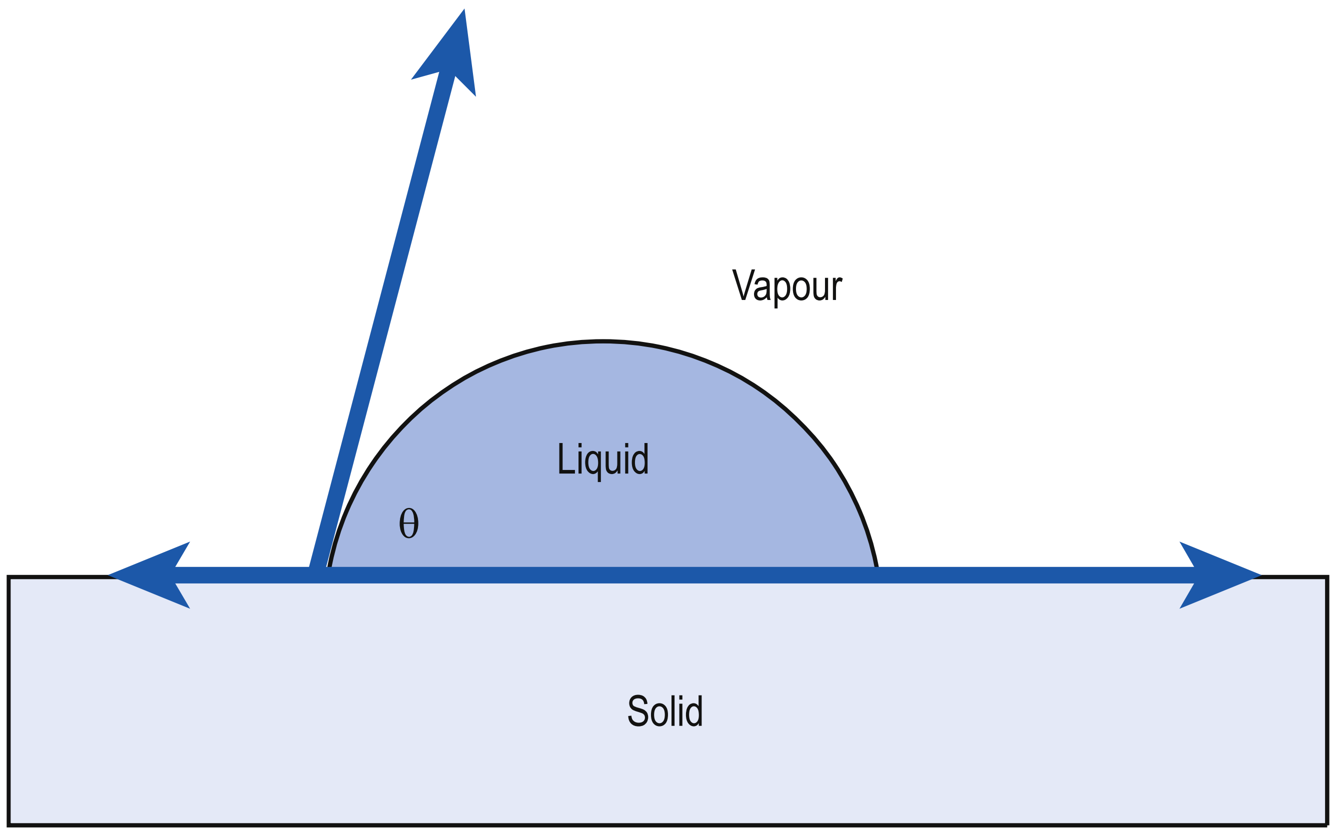


Fig. 4.10 Schematic representation of the sessile drop technique showing the contact angle (θ) measured when a drop is placed on a solid surface.

Fig. 4.11 shows the contact angles of two contact lenses. Note that the contact angle of lens B is considerably larger than that of lens A. However, it is important to bear in mind that the wettability of a given surface depends on a number of factors, including the surface tension of the test liquid and, as such, it is a property of a liquid–solid combination rather than of the solid surface alone.

The most commonly used techniques applied to contact lenses include sessile drop and captive bubble methods. In the sessile drop technique a drop of liquid (usually water) is applied to a dry or drying hydrogel lens surface in air (see Fig. 4.11). In the captive bubble technique, the hydrogel lens is submerged in liquid (usually water, saline or artificial tears) and a bubble of air is applied to the lens surface. The contact angles obtained for a lens–liquid combination are highly methodologically dependent (Maldonado-Codina and Morgan, 2007) and any reporting of contact angles should include the experimental details such as the method itself, the probe liquid and prior treatment of the material under test.

The sessile drop and the captive bubble techniques give discrepant results for a given sample because a different type of contact angle is measured in each technique: an advancing-type contact angle is measured in the sessile drop technique and a

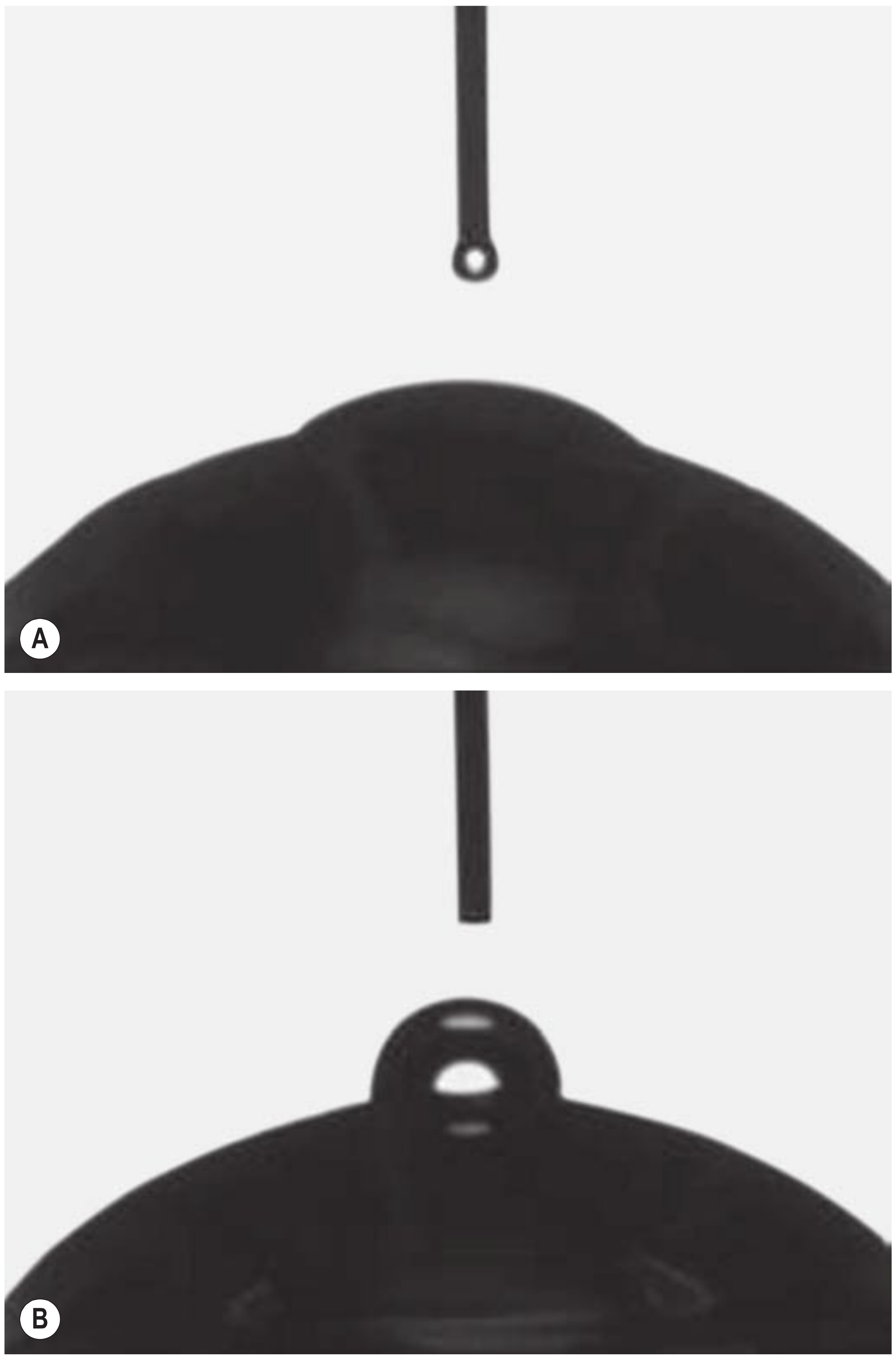


Fig. 4.11 Sessile drop contact angle images of a contact lens with a good wetting surface (A) and a poor wetting surface (B). Note the larger contact angle for lens with the poor wetting surface.

receding-type contact angle is measured in the captive bubble technique. Additionally, both of these techniques can be used to assess the hysteresis of a given material; that is, advancing and receding angles respectively can be obtained using the sessile drop technique alone or the captive bubble technique alone (Read et al., 2011).

The receding contact angle obtained in vitro is especially relevant when considering the performance of a contact lens in vivo. The advancing angle corresponds more to the establishment of the tear film, which is assisted mechanically by the eyelid. Conversely, the receding angle is thought to be important in the stability of the tear film between blinks.

Another aspect of the lens surface that has important clinical implications is its frictional characteristics. Friction is defined as the resistance that a solid surface encounters when it moves over another. In doing so, these solid surfaces can undergo 'wear and tear' which can be reduced if there is sufficient lubrication between the surfaces. In the eye, the tear film acts as such a lubricant between the eyelid margin conjunctiva and the ocular surface. The area of the eyelid margin conjunctiva that 'rubs' over the ocular surface has been termed the 'lid wiper' (Korb et al., 2002).

When a contact lens is in situ, the 'lid wiper' 'rubs' over the lens surface many thousands of times during a wearing day and it is thought that this interaction is highly important in governing the comfort of a lens – particularly its end-of-day comfort (Coles and Brennan, 2012). The frictional characteristics of a lens surface are a function of not only the lens material chemistry but also of how that surface interacts with the ocular environment. Dehydration, spoilation, poor tear film characteristics and irregularities of the ocular surface can all lead to increased friction between the lens and the eyelid margin during wear. These frictional properties are an important consideration in the overall design of a contact lens.

Coefficient of friction (CoF) laboratory measurements have now become commonplace for contact lens materials. The CoF is the ratio of the force needed to initiate or sustain sliding to the normal force holding the two surfaces together and in the laboratory some kind of lubricant would be required. As with many other laboratory set-ups, it is very difficult to simulate on-eye conditions and this is primarily why different CoF results have been obtained by different research groups carrying out these experiments (Ross et al., 2005; Roba et al., 2011).

WATER CONTENT

The EWC of a hydrogel lens is defined as:

$$\text{EWC} = \frac{\text{weight of water in polymer}}{\text{total weight of hydrated polymer}} \times 100$$

The EWC of a hydrogel may vary depending on the environmental conditions. For example, pH, tonicity and temperature may alter the EWC of a hydrogel. Increased temperature is an important consideration because there is a significant increase in temperature when a contact lens is taken from its packaging solution (normally at room temperature) and placed on the eye. Most contact lens hydrogels will undergo a small change in EWC when placed in solutions of different pH and osmolality, but these changes will be most pronounced in ionic materials.

The oxygen and ion permeability of a contact lens material are intimately associated with its EWC. This is discussed in more detail in the following sections.

The surface EWC of a contact lens can be measured using a soft contact lens refractometer (Efron and Brennan, 1987). This is a hand-held instrument that can be readily used in the clinical setting. It utilizes the inverse relationship between the refractive index and EWC of hydrogel materials. The measured refractive index of a contact lens is converted to percentage water in sucrose using the Brix scale. This approach does, however, have limitations in that it assumes that dehydrated hydrogels all have the same refractive index (i.e. that of dry sucrose). However, this assumption is not strictly true and the difference in refractive index of a particular hydrogel material and sucrose will lead to the difference between Brix measures and manufacturer-reported water contents.

Difficulties are also encountered with this instrument when attempting to measure the EWC of silicone hydrogel lenses. These lenses have a lower refractive index compared with hydrogels and their EWC is overestimated with the soft contact lens refractometer. Additionally, since it is surface EWC that is being measured with this instrument, it is unknown what effect the surface coatings on some of these lenses have on the final result.

British and International Organization for Standardization (ISO) standards specify both thermogravimetric and refractive index methods as valid techniques for measuring the EWC of a hydrogel lens (BSI, 2006a). The thermogravimetric method involves measuring the weight of a lens in the hydrated state and then remeasuring the lens in the completely dehydrated state. The disadvantages of this method are that it is time consuming and destroys the lens.

OXYGEN PERMEABILITY

Since the cornea receives most of its oxygen from the atmosphere, the oxygen transmissibility profile of a contact lens is one of its most important properties. Oxygen permeability is a property of the material itself and is described as the Dk, where D is the diffusivity of the material and k is the solubility of the material. The diffusivity is a measure of how quickly oxygen can move through a material, whilst the solubility is a measure of how much oxygen the material can hold. Oxygen permeability of a hydrogel will vary with temperature.

Oxygen permeability is governed by the EWC in hydrogels. This relationship is based on the ability of oxygen to pass through the water rather than through the material itself. The relationship between the EWC and oxygen permeability has been found to be (Morgan and Efron, 1998):

$$\text{Dk} = 1.67e^{0.0397\text{EWC}}$$

where e is the natural logarithm (Fig. 4.12).

In order to calculate the amount of oxygen that will move from the anterior to the posterior surface of a lens, the oxygen permeability (Dk) is divided by the thickness of the lens (t). The units of Dk have been traditionally known as Fatt units (after Professor Irving Fatt, who carried out much of the early work on oxygen permeability of contact lens materials) or Barrer, whereby:

$$\text{Dk (Barrer)} = 10^{-11}\,(\text{cm}^2 \times \text{mlO}_2) / (\text{s} \times \text{ml} \times \text{mmHg})$$

$$\text{Dk/t (Barrer/cm)} = 10^{-9}\,(\text{cm} \times \text{mlO}_2) / (\text{s} \times \text{ml} \times \text{mmHg})$$

However, the SI unit for pressure is the pascal (Pa). Because the unit mmHg is now becoming obsolete internationally, it is being advocated that the closest accepted metric unit of

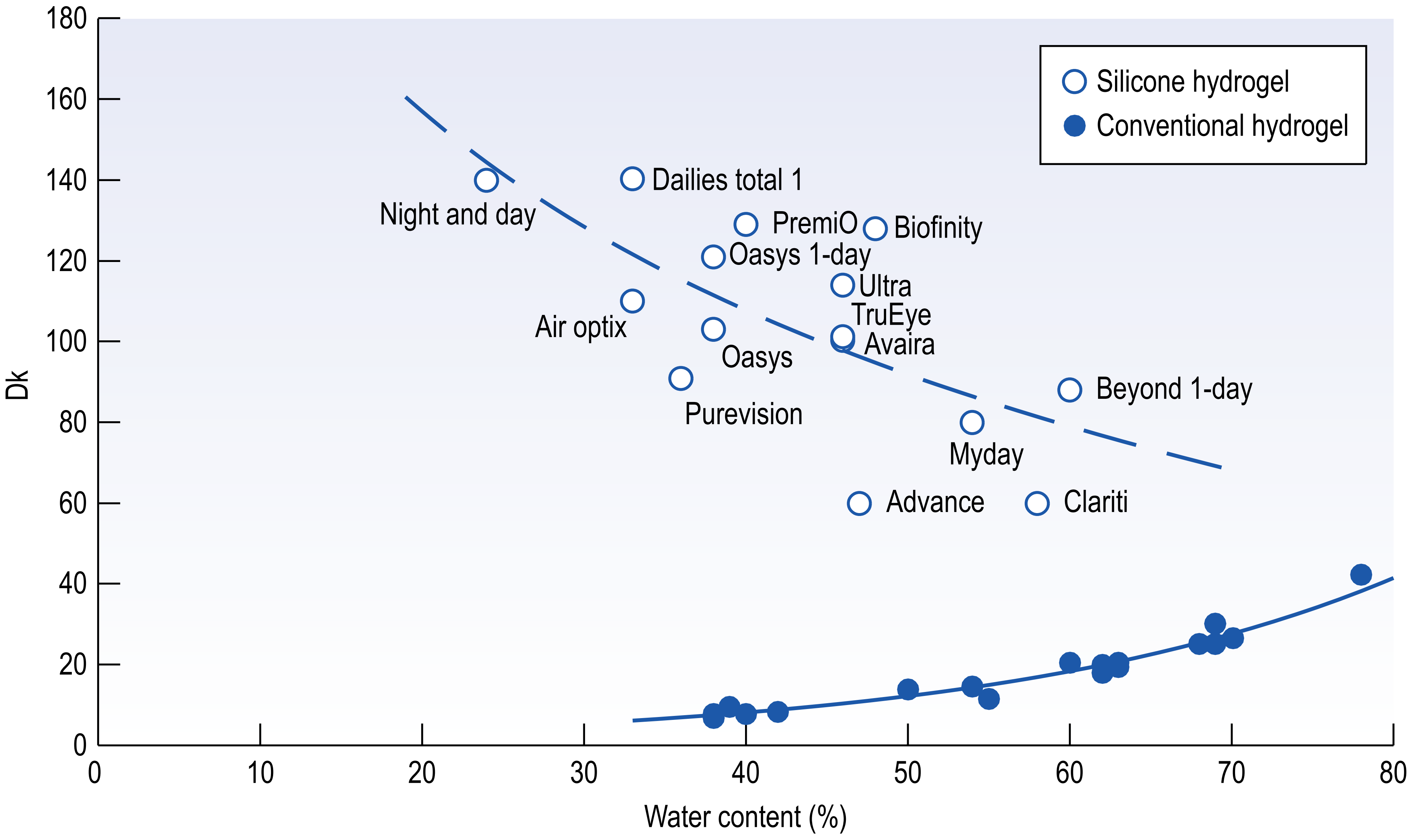


Fig. 4.12 Relationship between Dk and equilibrium water content for conventional hydrogel and silicone hydrogel lenses.

pressure – 100 Pa, or hectopascal (hPa) – should replace mmHg (BSI, 2006b). The new units are referred to as 'Dk units' in this latest British and international standard. When hPa is used, Dk and Dk/t values are quoted as below:

$$\text{Dk in 'Dk units'} = 10^{-11}\,(\text{cm}^2 \times \text{mlO}_2)\,/\,(\text{s} \times \text{ml} \times \text{hPa})$$

$$(\text{Dk/t}) \ \text{in 'Dk/t units'} = 10^{-9}\,(\text{cm} \times \text{mlO}_2)\,/\,(\text{s} \times \text{ml} \times \text{hPa})$$

The difficulty here is that converting from the traditional Barrer or Fatt units to ISO units involves multiplying Dk or Dk/t by the constant 0.75006. Thus, for example, a lens quoted with a traditional Dk/t of 40 units will have a revised ISO Dk/t of 30 units. It is understandable that such a 'downsizing' will be resisted by contact lens manufacturers, because higher numeric Dk/t are perceived clinically as being 'superior'.

FLUID AND ION PERMEABILITY

The development of silicone hydrogel materials has highlighted the importance of the so-called hydraulic permeability or water transport of a contact lens material. Essentially, a minimum level of hydraulic (as well as ionic) permeability is necessary in order to maintain adequate lens movement. This is important in allowing the post-lens tear film to re-form between blinks, thus reducing the likelihood of these quite elastic lenses from binding to the cornea. Water is able to move through a hydrogel in quite a different way to sodium ions; that is, it is more difficult for sodium ions to travel through the gel as in order to do so they must be accompanied by a shell of water (Tighe, 2004). In the eye, the sodium ion permeability of contact lens materials is particularly important as it is a major constituent of the tear film. Sodium ion transport is impeded in gels with water content below 20%.

REFRACTIVE INDEX

Ideally hydrogels fabricated for contact lens materials should have a refractive index similar to that of the cornea (i.e. near to 1.37). The variation of refractive index with EWC in hydrogels is almost linear, with most hydrogel refractive indices falling within 1.46–1.48 at 20% water content and 1.37–1.38 at 75% water content – that is, the refractive index decreases with increasing water content. Because of this relationship, it is possible to calculate the refractive index of a hydrogel if its EWC is known (and vice versa), which is the basis for the use of the soft contact lens refractometer, as discussed above. This relationship is well established for hydrogel lenses but not for silicone hydrogel lenses.

It is unlikely that a relationship between the refractive index and the water content will hold for all silicone hydrogel lenses on the market as many are based on completely different material chemistries. British and ISO standards recommend the use of an Abbé refractometer to measure the refractive index of a hydrogel contact lens (BSI, 2006a). However, other more automated instruments have been used for the assessment of hydrogel lens refractive index (Nichols and Berntsen, 2003; Lira et al., 2008).

SWELL FACTOR AND DIMENSIONAL STABILITY

The dimensional stability of a hydrogel lens refers to its ability to maintain its original dimensions under various conditions. It is dependent on any factor that will change the water content or swelling behaviour of the hydrogel. Factors that influence the swell factor include temperature, pH and tonicity. The swelling behaviour is particularly important during the manufacture of contact lenses in the dry state (e.g. when a soft contact lens is lathed). During the lathing process a smaller, steeper lens of greater power is made so that, when it is hydrated, it swells to the required dimensions and power required. It is vital, therefore, that the swell factors of the material are accurately known. The swell factor is described by the following relationship:

$$\text{Swell factor (SF)} = \text{wet dimension/dry dimension}$$

Initially it was thought that a hydrogel material swelled isotropically – that is, the same in all directions. With time it was found, however, that the consistently anomalous swelling behaviour of hydrogels could be explained only by specifying two swell factors. These swell factors are those in the diameter and axial (thickness) directions. From these, the value of the radial swell factor of a contact lens can be calculated using the following equation:

$$SF_{rad} = (SF_{dia})^2/SF_{ax}$$

where SF_{rad} is the radial swell factor, SF_{dia} is the diametral swell factor and SF_{ax} is the axial swell factor.

Soft Lens Materials

Soft lens materials can be conveniently divided into two main groups: (1) hydrogel materials (now sometimes referred to as low-Dk materials) and (2) silicone hydrogel materials (high-Dk materials).

HYDROGEL MATERIALS

Hydrogel lenses were developed as a result of the extraordinary pioneering efforts of Professor Otto Wichterle and Dr Drahoslav Lim of the Institute of Macromolecular Chemistry of the Czechoslovak Academy of Sciences in Prague in the mid 1950s. Wichterle and Lim were working on the synthesis of a new material that they hoped could be used for implantation into the human body. That material was poly(hydroxyethyl methacrylate) or pHEMA (Wichterle and Lim, 1960). They soon realized that the material had potential applications in the manufacture of contact lenses, but were prevented from researching such a project by the directors of the institute, who perceived this work as being a petty distraction from fundamental studies in chemistry. Wichterle was eventually forced to carry out his contact lens experiments at home and, despite such difficult circumstances, he successfully managed to produce the first spun-cast lens (made from his son's toy construction set) in 1961 (Wichterle and Lim, 1961). The enormity of his breakthrough for the contact lens industry cannot be understated.

pHEMA is made by polymerizing 2-hydroxyethyl methacrylate monomer with a cross-linker such as ethylene glycol dimethacrylate (EGDMA) (Fig. 4.13). Most of the hydrophilic behaviour of HEMA is due to the presence of the hydroxyl group (OH) at the end of the monomer. At this location in the resultant polymer hydrogen bonding with water molecules occurs, causing them to be drawn into the polymer matrix. The result is that contact lenses made from pHEMA contain approximately 40% water in the fully hydrated state.

Lenses fabricated from pHEMA were first distributed in western Europe in 1962, but sales were disappointing. In 1965, the National Patent Development Corporation bought the licence for the American rights to the technology from the Czechs. This was subsequently sold on to Bausch & Lomb, which at that time manufactured ophthalmic equipment and spectacle lenses. Bausch & Lomb significantly refined Wichterle's spin-casting process and finally obtained approval from the US Food and Drug Administration (FDA) for its pHEMA lenses in 1971. This time, the lenses became very popular very quickly – both practitioners and patients enjoyed the benefits of increased comfort, reduced adaptation time and easier fitting procedures compared with rigid corneal lenses, which were the main alternative. With time, more companies developed their own pHEMA lenses; however, it soon became clear that these lenses were not problem free. Most of these problems stemmed from the fact that the lenses caused hypoxia, but other complications relating to solution toxicity and lens spoliation were also common.

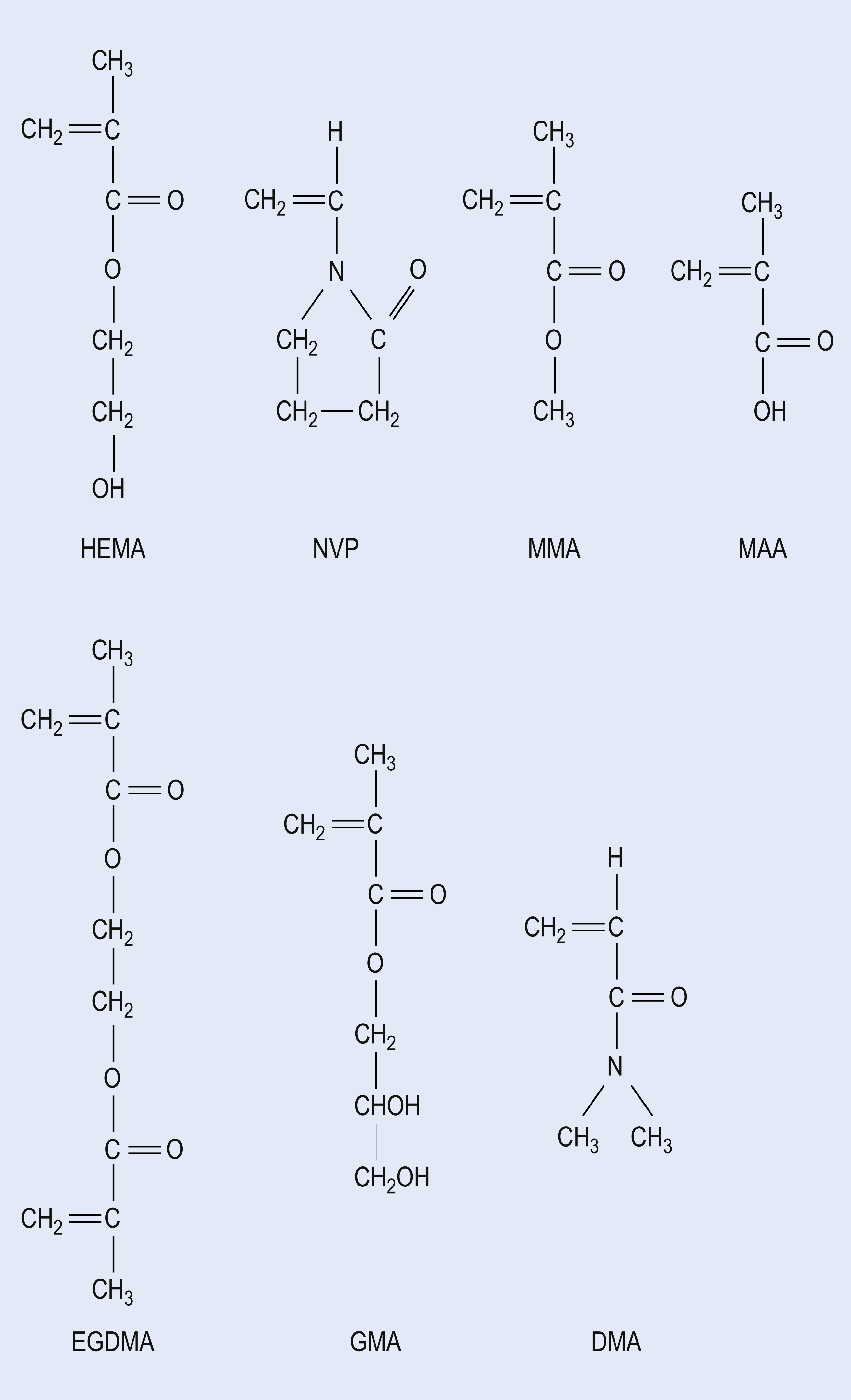


Fig. 4.13 Some of the monomers used in hydrogel lens materials. HEMA = hydroxyethyl methacrylate; NVP = N-vinyl pyrrolidone; MMA = methyl methacrylate; MAA = methacrylic acid; EGDMA = ethylene glycol dimethacrylate; GMA = glyceryl methacrylate; DMA = N,N-dimethyl acrylamide.

In hydrogel materials, oxygen is transported through the water channels in the lens, and not the polymer itself. Contact lens manufacturers, therefore, had two possible avenues to follow to increase the oxygen transmissibility of lenses: develop 'hyperthin' lenses, or develop materials with higher water content. Producing lenses that were thinner was a relatively straightforward matter for lens designers and several such lenses were launched, such as the Hydrocurve thin lens (Soft Lenses) in 1977 and subsequently the O3 series (Bausch & Lomb). These lenses were in the region of 0.035–0.06 mm thick, which was less than half the thickness of the original Bausch & Lomb pHEMA lenses.

Developing materials with a higher EWC led to the successful development of HEMA copolymers. One of the first successful copolymerizations was with N-vinyl pyrrolidone (NVP) (see Fig. 4.13). The amide (N—C=O) moiety is very polar and two molecules of water can become hydrogen-bonded to it. NVP-based copolymers lose the slippery feel of pHEMA and consequently can feel quite rubbery. These copolymers also tend to have relatively high evaporation rates of water, which may be seen as a problem for lens stability and comfort. This occurs because the amide group does not bind water as strongly as a hydroxyl group. In addition, these polymers are also significantly more temperature sensitive than pHEMA-based materials; that is, their parameters tend to change with increasing or decreasing temperature. This is important when fitting a lens as its parameters may change on-eye.

NVP-based lenses have also been associated with increased corneal staining (solution-induced corneal staining or 'SICS') and decreased comfort when used in conjunction with solutions containing higher levels of polyhexanide (Jones et al., 1997, 2002). This does not mean that polyhexanide-based solutions cannot be used with NVP-containing lenses, but rather that the interaction should be borne in mind and, if any significant corneal-staining or discomfort symptoms arise these can usually be treated simply by changing the solution to one containing a lower level of polyhexanide or one free from polyhexanide.

Most contact lens practitioners are familiar with methyl methacrylate (MMA) as the material from which 'hard lenses' are made (i.e. PMMA) (see Fig. 4.13). When MMA and NVP are copolymerized, a completely new material is obtained with very different characteristics to the HEMA/NVP (also known as HEMA/VP) copolymers. Depending on their composition, contact lenses made from MMA/VP copolymers can contain 60–85% water. MMA is very hydrophobic, but is useful in soft lens hydrogels as it gives the resultant polymers increased mechanical strength.

Another hydrophilic monomer that has been very successfully used in contact lens hydrogels is MAA (see Fig. 4.13). When added to a soft lens polymer formulation, it results in a soft lens with ionized groups (negatively charged) within the polymer matrix, allowing the lens to absorb more water. The higher the amount of MAA, the higher is the EWC of the resulting polymer. Amounts of MAA in the region of 1.5–2.5% will increase the water content of a HEMA material into the mid-water-content range of 50–60%, thereby allowing oxygen permeability to increase significantly. Another advantage of these ionic lenses is that, although they attract large quantities of protein (particularly positively charged lysozyme) (Suwala et al., 2007), a large proportion of these proteins are in their natural, non-denatured form (Subbaraman et al., 2006; Suwala et al., 2007; Subbaraman and Jones, 2010), which is thought to be beneficial in terms of contact-lens-related complications such as contact lens papillary conjunctivitis and, very importantly, in terms of their antimicrobial action (Brennan and Coles, 2008).

Unfortunately, using MAA to increase the water content of a polymer also has its disadvantages. These include:

- A lens that is extremely sensitive to changes in tonicity (McCarey and Wilson, 1982): the Na^+ ions present in saline solution have the effect of 'shielding' the carboxylate anions. In hypotonic solutions (e.g. pure water), since these shielding ions are present to a far lesser degree, more chain repulsion will occur, which increases the swelling of the network and consequently the EWC of the material. In hypertonic solutions, the reverse situation occurs and the material network shrinks, causing its EWC to decrease.
- A pH-sensitive lens (McKenney, 1990): if the pH of the solution in which the lens is immersed is decreased (i.e. the hydrogen ion concentration is increased), the carboxylate anions are more shielded and the network becomes less expanded. This will cause a decrease in the lens EWC.
- Dimensional instability when the lens is heat disinfected.

Glyceryl methacrylate (GMA) is more hydrophilic than HEMA owing to the fact that the monomer contains two hydroxyl groups (see Fig. 4.13). This monomer has been used in contact lens materials in two main ways. The first method has used GMA in combination with MMA to produce materials that have water contents in the range of 30–42%. These materials are thought to be stiffer and stronger than pHEMA hydrogels, but their oxygen permeabilities are not ideal for in-eye use.

The second method has been to use GMA in combination with HEMA to produce a high-water non-ionic contact lens materials (up to approximately 70% has been possible). These contact lenses are said to be 'biomimetic' – that is, they are claimed to improve biocompatibility by imitating the hydrophilic properties of mucin. Manufacturers also suggest that these lenses show a low rate of dehydration and a rapid rate of rehydration (i.e. they have good 'water balance ratios'). In addition, the materials are thought to be relatively deposit-resistant and seem to be insensitive to pH changes in the range of pH 6–10. An example of such a lens is the hioxifilcon A material used in the Clear 1 Day lenses manufactured by Clearlab. Another example of a so-called biomimetic lens is the Proclear lens (Coopervision), which contains phosphoryl choline (PC) and HEMA. PC is said to mimic the natural chemistry of cell membranes.

In the early 1970s an English optometrist, John de Carle, proposed that if the EWC of hydrogel lenses could be sufficiently increased then these lenses could be worn successfully on an overnight or extended-wear basis. He developed the first extended wear lens to be distributed in the UK, known as Permalens (de Carle, 1975). The lens material had an EWC of 71% and was made from a HEMA/VP/MAA copolymer. In 1981 the lens was given FDA approval for 'extended wear' of up to 30 days along with another lens, the Hydrocurve II (Wesley Jessen).

Slowly, other lenses were given approval for extended wear during the 1980s, but along with the increase in demand for these lenses came an increase in complications. In 1989 studies were published showing that the risk of microbial keratitis was 5–15 times greater for extended wear than for daily wear (Poggio et al., 1989; Schein et al., 1989). As a result, the FDA recommended that extended wear be limited to six consecutive nights and, with that, the enthusiasm for extended wear died down to some extent until the emergence of silicone hydrogel lenses in the late 1990s.

Table 4.1 lists some of the most common hydrogel lenses on the market and groups them into their appropriate FDA classification (see Appendix 4.1, below, for details on the classification of hydrogels).

Most of the work that has been carried out on 'improving' hydrogel lenses has been channeled towards developing them into disposable lenses and especially into daily disposable lenses. In order to achieve this, manufacturers have invested in more sophisticated automated manufacturing technologies to meet demand and make their production economically viable. This has been no easy task and it should be emphasized just how important these hydrogel materials still are to the contact lens industry today.

Additionally, 'enhanced' daily disposable lenses have been introduced onto the market, such as 1-Day Acuvue Moist (Johnson & Johnson), Dailies AquaComfort Plus (Alcon) and SofLens daily disposable (Bausch & Lomb). These lenses utilize techniques

TABLE 4.1 Selected Hydrogel Lenses

Name	Manufacturer/Supplier	Principal Components	EWC (%)	USAN Nomenclature
FDA GROUP 1 (<50% EWC <0.2% IONIC CONTENT)				
Biomedics 38	Coopervision	HEMA	38	Polymacon
Durawave	UltraVision CLPL	HEMA, GMA	49	Hioxifilcon B
Menicon Soft	Menicon	HEMA, VA, PMA	30	Mafilcon A
Optima Toric	Bausch & Lomb	HEMA/VP	45	Hefilcon B
Sauflon 38	Sauflon	HEMA	38	Polymacon
SofLens 38	Bausch & Lomb	HEMA	38	Polymacon
FDA GROUP II (>50% EWC <0.2% IONIC CONTENT)				
Biotrue One day	Bausch & Lomb	HEMA, VP	78	Nesofilcon A
Dailies AquaComfort Plus	Alcon	PVA	69	Nefilcon A
Focus Dailies All Day Comfort	Alcon	PVA	69	Nefilcon A
Omnifex	Coopervision	MMA, VP	70	Lidofilcon-A
Proclear	Coopervision	HEMA, PC	62	Omafilcon B
Sauflon-55	Sauflon	HEMA, VP	55	N/A
SofLens daily disposable	Bausch & Lomb	HEMA, VP	59	Hilafilcon B
UltraWave	UltraVision CLPL	HEMA, GMA	57	Hioxifilcon A
FDA GROUP III (<50% EWC <0.2% IONIC CONTENT)				
Accusoft*	Ophthalmos	HEMA, PVP, MAA	47	Droxifilcon-A
Comfort Flex*	Capital Contact Lens	HEMA, BMA, MAA	43	Deltafilcon-A
Soft Mate II*	CIBA Vision	HEMA, DAA, MAA	45	Bufilcon-A
FDA GROUP IV (>50% EWC >0.2% IONIC CONTENT)				
Acuvue 2	Johnson & Johnson	HEMA, MAA	58	Etafilcon A
1-Day Acuvue Moist	Johnson & Johnson	HEMA, MAA	58	Etafilcon A
Biomedics 55UV	CooperVision	HEMA, MAA	55	Ocufilcon D
Freshlook ColorBlends	Alcon	HEMA, MAA	55	Phemfilcon A
Frequency 55	CooperVision	HEMA, MAA	55	Methafilcon A
Permalens*	CIBA Vision	HEMA, VP, MAA	71	Perfilcon-A

*No longer available.

FDA = Food and Drug Administration; EWC = equilibrium water content; HEMA = 2-hydroxyethyl methacrylate; VP = N-vinyl pyrrolidone; MMA = methyl methacrylate; PC = phosphorylcholine; GMA = glyceryl methacrylate; MAA = methacrylic acid; VA = vinyl acetate; PMA = polymethyl acrylate; PVA = polyvinyl alcohol; PVP = polyvinyl pyrrolidone (i.e. graft copolymer); BMA = butyl (probably isobutyl) methacrylate; DAA = diacetone, acrylamide; USAN = United States adopted name.

of macromolecular entrapment and/or release of hydrophilic surface-active polymers at the lens surface in order to improve end-of-day comfort by stabilizing the pre-lens tear film.

The Dailies AquaComfort Plus lens is manufactured from nelfilcon A, which consists of a cross-linked functionalized polyvinyl alcohol (PVA) macromer with the addition of non-functionalized PVA (Winterton et al., 2007). This unfunctionalized PVA macromer is free to elute from the lens into the tear film with each blink. This PVA is thought to emerge from the lens matrix as 'strands' at the lens surface, and it is this effect together with the effect of soluble PVA in the tear film that is referred to as the 'surface modification' of these lenses. The released PVA may improve lens comfort by decreasing the surface tension of the tears, or by mimicking mucin, found naturally in the tear film (Mahomed et al., 2004). The blister packaging also contains hydroxypropyl methylcellulose (HPMC), which is a lubricating agent used to improve comfort on lens applications, as well as polyethylene glycol (PEG), which is a hydrophilic wetting agent with a high affinity for PVA used for enhancing comfort throughout the day.

PVA and polyvinyl pyrrolidone (PVP) are common soluble polymeric components in comfort drops and artificial tears and have a viscous consistency at elevated concentrations and molecular weights, giving them good surface spreading characteristics. The 1-Day Acuvue Moist lens is manufactured from the etafilcon A polymer (HEMA/MAA) together with the incorporation of small concentrations of low-molecular-weight PVP into the ionic material network. Here the PVP is 'locked' into the lens matrix and is not released from the lens during wear. The PVP is adsorbed on to the preformed lens surface after manufacture from solution. The lens packaging states that the lenses are supplied in 'buffered saline with povidone'. Povidone is another name for PVP. PVP is quite polar and it is likely to be relatively strongly attracted to the etafilcon material, potentially providing a mechanism for its retention on the lens surface. The persistence of the PVP at the lens surface during wear has been verified by Ross et al. (2007), who have also described the PVP as being in a predominantly 'looped structure' across the lens surface. The PVP is thought to reduce the coefficient of friction of the lens surface

The SofLens daily disposable lens is modified by the adsorption of Tetronic 1107 – a hydrophilic surface-active polymer composed of ethylene oxide/propylene oxide block copolymer – onto the lens surface. The Tetronic at the surface lowers the coefficient of friction of the lens, but it has been shown to be progressively lost from the surface during wear (Ross et al., 2007). It is likely, therefore, that the Tetronic is held by weak forces at the lens surface, which would explain the lowest in-eye persistence of three 'enhanced' lenses investigated by Ross et al. in 2007.

SILICONE HYDROGEL MATERIALS

When Holden and Mertz (1984) defined the critical oxygen levels in order to avoid corneal oedema for daily and extended wear they concluded that 24.1 Barrer/cm was the oxygen transmissibility required for daily wear and 87 Barrer/cm was that required for overnight wear. These values were re-evaluated by Harvitt and Bonanno (1999), who found that the minimum oxygen transmissibility required to avoid anoxia throughout the entire cornea was 35 Barrer / cm for the open eye and 125 Barrer / cm for the closed eye.

Fig. 4.12 shows the relationship between the EWC and the Dk of hydrogels and silicone hydrogels. From the graph, it is obvious that there is an upper limit to how much oxygen permeability can be attained simply by increasing the EWC of hydrogel materials. A hydrogel with a theoretical EWC of 90% and a central thickness of 0.1 mm would have an oxygen transmissibility in the region of 60 Barrer / cm, which still falls far short of that required to avoid additional overnight corneal oedema. Such a lens would need to be in the region of 0.06 mm thick, which is unrealistic from both a manufacturing and a clinical point of view (Holden et al., 1986).

If reducing the thickness of lenses made from hydrogels was not an option for achieving success in extended wear, then polymer scientists had to come up with an altogether new kind of material. That material was silicone. The element silicon (Si) is the most abundant element on earth after oxygen (e.g. in the form of silicates or oxides such as sand and clay). Silicones are organic compounds of silicon and oxygen.

Incorporating silicone into contact lens materials was not a new concept when scientists began trying to produce silicone hydrogels. Indeed, the first material to be used in contact lenses was silicone dioxide (glass). Additionally, silicone rubber (polydimethyl siloxane, PDMS) (Fig. 4.14) has been used with limited success as a contact lens material in the form of silicone elastomer lenses. These lenses have not become popular mainly because of lens-tightening and surface wettability problems (PDMS is extremely hydrophobic) (Josephson and Caffery, 1987). PDMS has an oxygen permeability in the region of 600 Barrer but is unwettable by tears, deposits high degrees of lipid and needs to be surface treated. Surface treatments of silicone elastomer lenses have not been particularly successful in the past because Si—O chains have a tendency to rotate very easily and any hydrophilic parts of a newly treated surface tend to disappear inside the polymer.

Silicon, however, has been very successfully incorporated into rigid lens materials and it was this development that proved to be a key milestone in the subsequent development of silicone hydrogel materials. The work of Norman Gaylord at Polycon Laboratories drove the development of the first siloxane-based rigid lens material that merged the properties of MMA with the increased oxygen performance of silicone rubber (Gaylord, 1974, 1978). The resultant siloxymethacrylate monomer was tris(trimethylsiloxy)-methacryloxy-propylsilane (see Fig. 4.14) and is more commonly referred to as TRIS.

The patent literature shows that combining silicone with hydrogel monomers has been a goal for polymer scientists since the late 1970s. The biggest obstacle to this approach, however, is that silicone is hydrophobic and poorly miscible with hydrophilic monomers, resulting in opaque, phase-separated materials. In order to solve this problem, two main approaches have been utilized (Tighe, 2004). The first approach involves the insertion of polar groups into the section of the TRIS molecule, arrowed in Fig. 4.14, in order to aid its miscibility with hydrophilic monomers (Tanaka et al., 1979; Künzler and Ozark, 1994).

The second approach is that of utilizing macromers. Macromers are large monomers formed by preassembly of structural units that are designed to bestow particular properties on the final polymer (Tighe, 2004). This is illustrated in Fig. 4.15 with an example from an Alcon patent (Nicolson et al., 1996) that contains poly(fluoroethylene oxide) segments and oxygen-permeable polysiloxane units. Fig. 4.12 demonstrates the relationship between Dk and EWC for silicone-containing

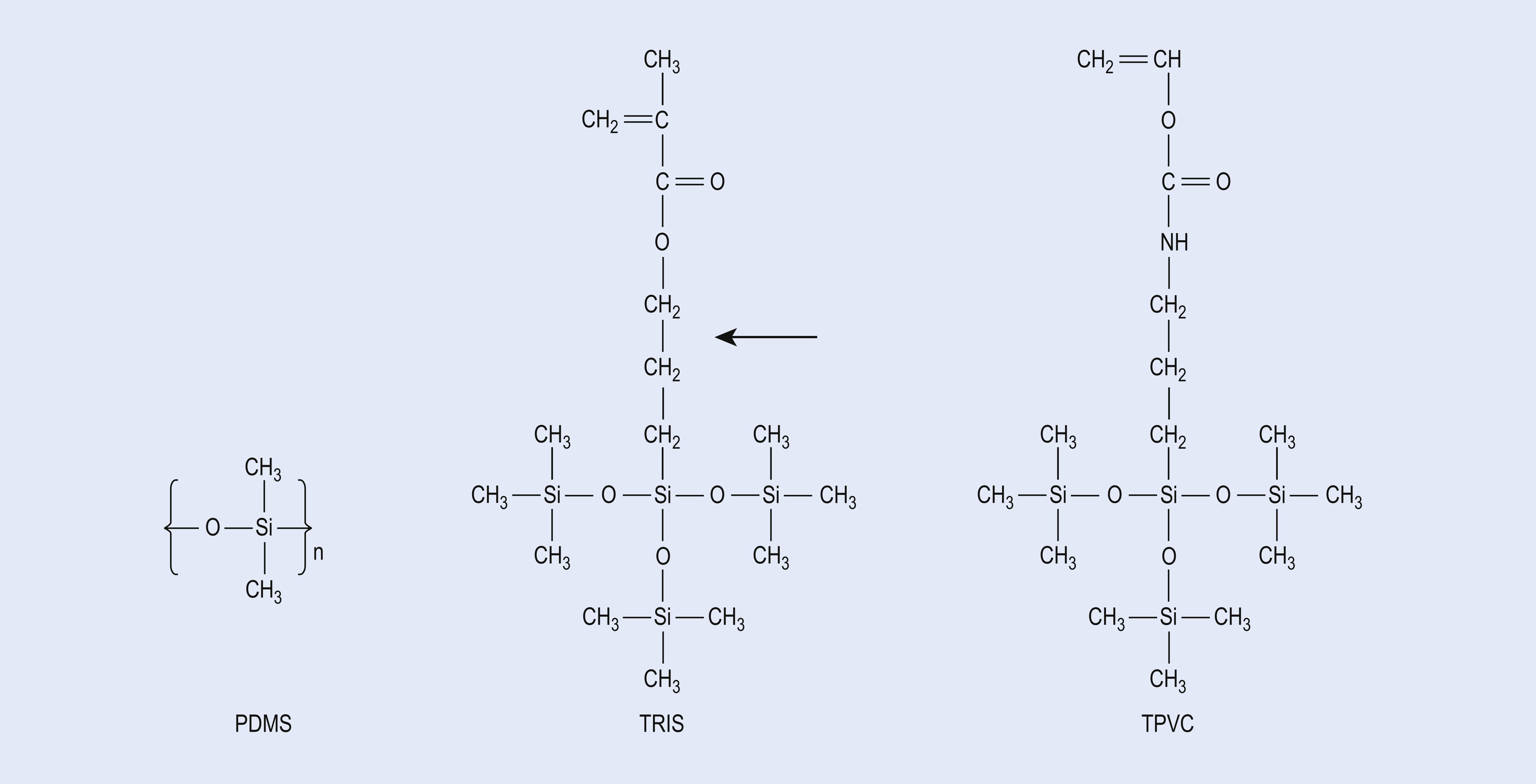


Fig. 4.14 Silicone-based materials. PDMS = polydimethyl siloxane; TRIS = tris(trimethylsiloxy)-methacryloxy-propylsilane; TPVC = carbamate-substituted TRIS.

hydrogels based on TRIS, highlighting the benefits of increased oxygen performance.

The first two silicone hydrogels were launched in the late 1990s – the PureVision lens (Bausch & Lomb) and the Air Optix Night and Day lens (Alcon) and are now commonly referred to as 'first-generation' silicone hydrogels. Both were licensed for 30 days of continuous wear (Table 4.2). The exact compositions of these materials are proprietary, but the USAN-registered components of the balafilcon A material show that it is based on a carbamate-substituted TRIS-based material known as TPVC (see Fig. 4.14). The TPVC is then copolymerized with NVP to form the balafilcon material.

The Air Optix Night and Day lens (lotrafilcon A) (Table 4.2) is 'biphasic'. Tighe (2004) describes the lens as being a fluoroether macromer copolymerized with TRIS and N,N-dimethyl acrylamide (DMA) in the presence of a diluent. Its biphasic (two-channel) structure means that oxygen and water permeability channels are not reliant on each other. The silicone-containing phase allows passage of oxygen whilst the water phase primarily allows the lens to move.

Without further treatment both of these first-generation silicone hydrogel lenses would be unsuitable for wear owing to the fact that the resultant material surfaces are very hydrophobic. In order to overcome this problem, both lenses are surface treated using gas plasma techniques. High-energy gases or gas mixtures (the plasma) are used to modify the lens surface properties without changing the bulk properties. The result for the balafilcon lens is that surface wettability is gained via plasma oxidation, which produces glassy silicate islands on the lens surface.

The lotrafilcon lens is coated with a dense 25 nm thick coating. Both resultant surfaces have low molecular mobility, which minimizes the migration of hydrophobic silicone groups to the surface. However, despite these surface modifications, wettability problems with these lenses were reported. It is generally accepted that silicone hydrogel lenses have inferior wettability compared with hydrogels, which occurs as a result of the hydrophobic interaction of silicone with the tear film.

Another important difference between these first-generation silicone hydrogel materials and hydrogels is that they have significantly greater elastic moduli (i.e. they are 'stiffer'). Such mechanical characteristics mean that the lenses are easy to handle, but have also been implicated in the aetiology of a number of clinical complications (Dumbleton, 2003). These include higher incidences of superficial epithelial arcuate lesions, mucin balls and CLPC (in particular, localized CLPC compared with generalized CLPC), especially with continuous wear of these lenses (Skotnitsky et al., 2002). The stiffness of the material may contribute to the mechanical irritation of the lens rubbing against the conjunctiva of the upper eyelid producing a localized response.

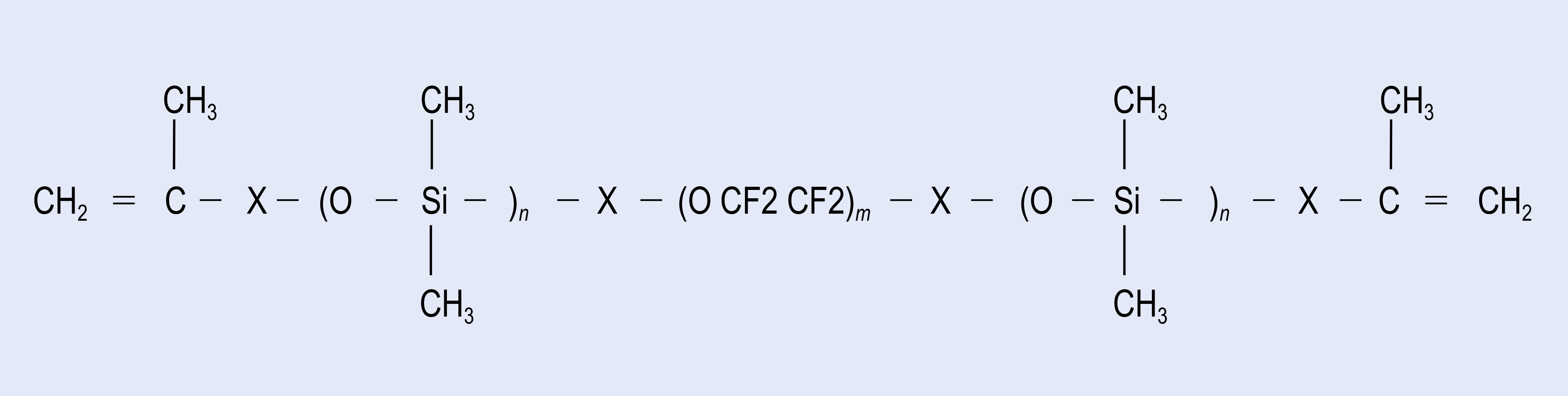
The design of a lens, and in particular the edges, may also have an impact on ocular compatibility. It has been suggested that the design of the lens edge in conjunction with the mechanical properties of silicone hydrogel lenses may be responsible for increased conjunctival staining and conjunctival epithelial flaps observed with these lenses (Loftstrom and Kruse, 2005). A knife-point edge or chisel-shaped edge may cause more conjunctival staining and flap formation than a round edge by 'carving' into the conjunctival tissue (Back, 2007). It has been proposed that certain edge designs incorporating localized increases in posterior edge lift, reduced peripheral thickness or peripheral channels may reduce the pressure on the conjunctiva (Back, 2007). However, more recent work has suggested that lenses that produce more circumlimbal staining are not associated with reduced levels of comfort (Maissa et al., 2012).

In an attempt to improve on the problems encountered with these first-generation lenses, manufacturers have engaged in a programme of research aimed at manufacturing silicone hydrogel lenses with improved mechanical and surface characteristics. This has resulted in the gradual emergence of 'second-generation' and 'third-generation' silicone hydrogel lenses such as Acuvue Oasys, 1-Day Acuvue TruEye, Avaira, Clariti, Dailies Total 1 and MyDay lenses (see Table 4.2).

The main advantage of these newer silicone hydrogels compared with the early silicone hydrogels is that they have increased water contents, reduced moduli and do not need to be surface treated. The mechanical and surface properties of the newest lenses are now similar to that of hydrogels (see Table 4.2). Recent clinical work indicates that there may be a lower incidence of CLPC with these lenses (Maldonado-Codina et al., 2004).

Some of the lenses in Table 4.2 are based on materials containing TRIS-like components. Acuvue Advance and Acuvue Oasys are based on Tanaka's original patent (following its expiration after 25 years) using a modified TRIS molecule, a silicone macromer and hydrophilic monomers such as HEMA and DMA. Alcohol is used as a solvent to aid the miscibility of these ingredients and is then extracted following polymerization. High-molecular-weight PVP is the internal wetting agent (the Hydraclear) used in these lenses, which is entangled and therefore 'entrapped' within the lens matrix and which allows them to be manufactured without requiring a surface treatment (Maiden et al., 2002; McCabe et al., 2004). The PVP essentially works by shielding the silicone from the tear film at the lens interface.

The Biofinity (comfilcon A) and Avaira lenses (enfilconA) are not based on TRIS chemistry. They are comprised solely of silicon-containing macromers and require no surface treatment or wetting agent. The patents surrounding the materials refer to a monofunctional macromer (which contains only one double bond taking part in the polymerization process) being



$$CH_2 = \overset{CH_3}{C} - X - (O - \underset{CH_3}{\overset{CH_3}{Si}} -)_n - X - (O\,CF2\,CF2)_m - X - (O - \underset{CH_3}{\overset{CH_3}{Si}} -)_n - X - \overset{CH_3}{C} = CH_2$$

Fig. 4.15 Typical siloxy-containing macromer (macromonomer) structure.

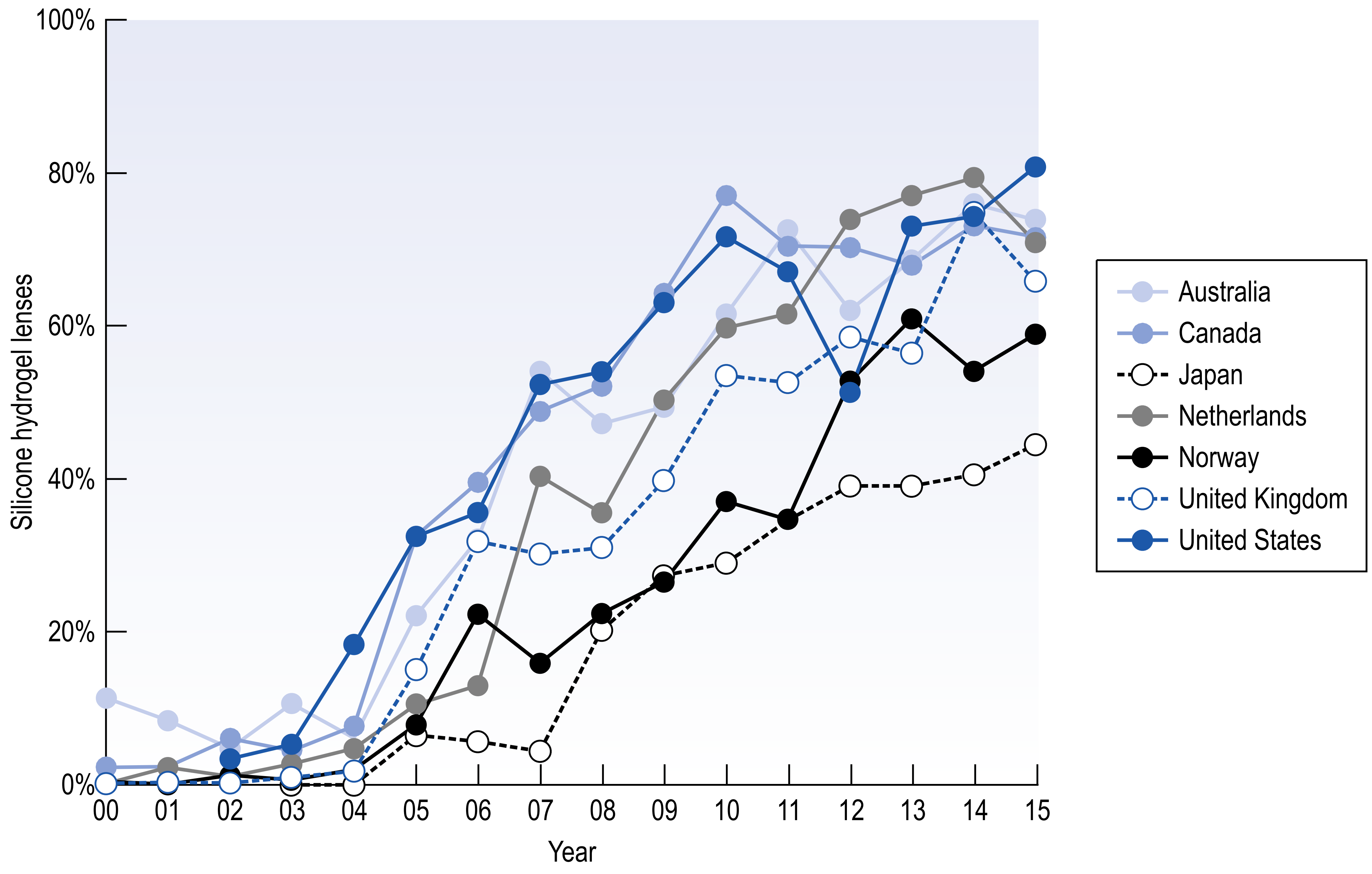


Fig. 4.16 Extent of silicone hydrogel contact lens fitting as a percentage of all soft lenses prescribed in seven nations between 2000 and 2015.

combined with another rubber-like siloxy macromer, resulting in a material with much longer chains (higher molecular weight) compared with the other silicone hydrogels (Iwata et al., 2005, 2006). The patents also discuss other hydrophilic monomers, which are presumably the key to why these materials do not need to be surface treated.

The introduction of second- and third-generation lenses has seen a significant rise in the number of silicone hydrogel lenses being prescribed on a daily-wear basis in addition to the introduction of daily disposable silicone hydrogel lenses (Morgan et al., 2016) (Fig. 4.16).

Classification of Soft Lens Materials

There are two main classification systems for soft contact lens materials. These classification systems are expanded upon in Appendix 4.1, below.

Conclusion

A basic understanding of the materials from which contact lenses are made as well as their behaviour is vitally important to any contact lens practitioner as it is likely to form an important aspect of patient management. Soft contact lenses have come a long way since the pioneering efforts of Professor Otto Wichterle in the late 1950s in terms of material, design and the way they are manufactured. Thick pHEMA lenses that were replaced every few years are now a thing of the past.

Whilst extended-wear hypoxia-related problems with hydrogels have been resolved with the introduction of silicone hydrogel materials, a number of mechanical and surface material-related complications still remain, despite the introduction of second- and third-generation polymers. For daily wear, there has been somewhat of a renaissance towards fitting hydrogel materials in recent years. This has come about because of the lack of evidence for increased comfort with silicone hydrogels, the lack of evidence to show that significant pathology results owing to oxygen levels reaching the anterior eye during daily wear and the confirmation that the incidence of microbial keratitis is no different between the two lens material groups. Future development of soft contact lens materials is likely to concentrate on trying to resolve the issues of inflammation and infection, improving lens comfort (particularly towards the end of the day), enhancing post-lens tear exchange and improving surface wettability.

ACKNOWLEDGEMENTS

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Access the complete references list online at http://www.expertconsult.com.

APPENDIX 4.1

CLASSIFICATION OF SOFT LENS MATERIALS

Food and Drug Administration (FDA) Classification System

The FDA classification system for soft lens materials is shown in Table 4A.1. The classification system groups lens materials based on their water content and physical charge. For many years the classification system consisted of four hydrogel groups. However, since silicone hydrogels were introduced, this classification system has not been ideal because these lenses are fundamentally different in their material chemistry. As a result, a fifth group for silicone hydrogels has been introduced.

The ISO Classification System

BS EN ISO 18369-1/DAM1:2009 sets out the new international standard method for the classification of a contact lens material given as a six-part code as follows:

(prefix) (stem) (series suffix) (group suffix) (Dk range) (surface modification code)

For soft lens materials, the classification denotes whether the material is ionic and the range in which the water content of the material lies. The presence or absence of surface modifications is also indicated.

The prefix is a term assigned to a material to designate a specific chemical formulation. Use of this prefix, which is administered by the United States Adopted Names (USAN) Council, is optional for all countries other than the USA.

Two types of stem are used. The filcon stem is affixed to the prefix and is applied for materials that contain ≥10% water by mass (hydrogel materials). Focon is applied to materials containing ≤10% water by mass (i.e. non-hydrogel materials).

The series suffix is also administered by the USAN council, and is used in cases in which the original ratio of the monomers of an existing contact lens polymeric material is changed to make a new material. In this case, the capital letter A is added after the stem designation. Subsequent changes in monomer ratio are designated by the next letter of the alphabet. These letters are used to differentiate copolymers of unchanged monomer units, but with different ratios. It can be omitted if there is only one formulation.

The group suffix, represented by a Roman numeral, indicates the range of water content and ionic character of the material (Table 4A.2).

Table 4A.3 shows how the oxygen permeability of the materials is classified.

The modification code, designated by a letter m, denotes whether the lens has a surface modification that renders the surface characteristics different to the bulk material. Such treatments include plasma treatment, acid/base hydrolysis and incorporation of a material that migrates to the surface. Certain types of tinted lens may also be considered surface modified. In the case of an unmodified surface, this suffix is omitted.

TABLE 4A.1 FDA Classification System for Soft Lens Materials

Group	Material
I	Low-water-content (<50%), non-ionic polymers
II	High-water-content (>50%), non-ionic polymers
III	Low-water-content (<50%), ionic polymers
IV	High-water-content (>50%), ionic polymers
V	Silicone hydrogel materials

TABLE 4A.2 BS EN ISO Hydrogel Suffix Groups

Group Suffix	Material
I	Low-water-content, non-ionic: materials that contain less than 50% water and contain 1% or less (expressed as mole fraction) of monomers that are ionic at pH 7.2
II	Medium- and high-water-content, non-ionic: materials that contain 50% water or more, and contain 1% or less (expressed as mole fraction) of monomers that are ionic at pH 7.2
III	Low-water-content, ionic: materials that contain less than 50% water and contain greater than 1% (expressed as mole fraction) of monomers that are ionic at pH 7.2
IV	Medium- and high-water-content, ionic: materials that contain 50% water or more, and contain greater than 1% (expressed as mole fraction) of monomers that are ionic at pH 7.2
V	Enhanced oxygen permeable materials (e.g. silicone hydrogel)

TABLE 4A.3 BS EN ISO Hydrogel Dk Groups

Group	Dk Range (ISO Dk Units)
0	<1
1	1–15
2	16–30
3	31–60
4	61–100
5	101–150
6	151–200
7, etc.	Increasing in increments of 50 Dk

Example

In order to demonstrate the BS EN ISO classification system, the 1-Day Acuvue Moist lens would be classified as follows:

Prefix: eta
Stem: filcon
Series suffix: A
Group suffix: IV
Dk range: 2
Modification code: none

The lens can, therefore, be classified as (etafilcon A) (IV) (2).

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5

Soft Lens Manufacture

NATHAN EFRON

Introduction

Three techniques can be employed to manufacture soft contact lenses – lathe cutting, spin casting and cast moulding. As medical devices that rest against the highly sensitive eyeball, contact lenses need to be of the highest quality in terms of their physical construction. As devices that correct optical defocus, the optical quality of contact lenses must also be of the highest order. At the same time, it must be recognized that companies will manufacture contact lenses only if they are profitable; the dominant forces in the market dictate that these high-quality products must be delivered at minimal cost, and one consequence of this is a simplification of lens parameters to streamline the high-volume process.

Methods of Manufacture

A key requisite of any technology employed to manufacture a medical appliance is that the final product is safe, predictable and of high quality, so that it meets the intended need. The three technologies discussed below have been developed to meet these requirements.

LATHE CUTTING

This process essentially involves the use of a special contact lens lathe to cut an anhydrous cylindrical button of material (xerogel) into the required shape, and then hydrating this to form the finished soft lens. Lathe manufacture ranges from labour-intensive, manual-based cutting systems to sophisticated and fully automated manufacturing lines, depending on the capital budget or skill levels available (Fig. 5.1). Even with the use of automation, however, the number and variability of manufacturing steps that are necessary for lathe cutting means that manufacturing soft lenses using this technology is necessarily more expensive than using spin casting or cast moulding.

Therefore, lathe cutting is generally reserved for the production of custom-ordered or extreme range lenses that contain design features not amenable to mass production, such as lenses of high spherical power and / or high toric power, or aberration-correcting soft lenses for keratoconus (Marsack et al., 2008).

The raw xerogel is supplied to the lens manufacturer in the form of 'rods' or 'buttons'. A rod is a solid cylindrical piece of xerogel, about 16 mm in diameter and 400 mm long. The rod is then sliced, orthogonally to the long axis, into buttons about 10 mm thick. More commonly, the xerogels are fabricated and supplied in button form. When this occurs buttons have usually been pre-trimmed to an industry standard size so that they can be machined in most of the available lathes.

The button is first secured to a back surface lathe in a clamp or 'collet', and this assembly is set spinning at a high rate (typically 8000–12 000 rpm) about its central axis. A diamond-tipped tool cuts the posterior surface lens shape into the button. A second diamond tool advances from the side to reduce the diameter to the required size. The surface is rendered smooth by either fine machining or polishing. Modern sophisticated lathes are capable of cutting xerogel surfaces to a tolerance of 8–15 nm. Such smooth surface finishing precludes the need for polishing and is preferred when non-spherical surface geometries are being generated. This approach also serves to preserve the consistency of one surface to the next. The dimensions of the lathed surface are calculated to allow for eventual expansion when the xerogel is later hydrated.

The button is removed from the collet and the cut posterior surface of the button is mounted onto a support tool of a front surface lathe, using low-melting-point wax. It is essential during this process that the button is mounted and fixed in an absolutely concentric and level aspect to the support tool in order to minimize unwanted prism being introduced by the front surface cutting. A diamond-tipped tool cuts the anterior surface down to the required thickness, and the surface is smoothed. The most advanced lathes offer 'W' axis cutting options that can generate rotationally non-symmetric surfaces whilst the primary front surface is being cut. Polishing tools may be used to smooth the lens edge, although some advanced lathes obviate this step.

After inspecting and measuring all relevant dry lens parameters, the lens is hydrated in normal, unpreserved saline until it is fully equilibrated and impurities have been extracted. The hydrated lens is re-inspected for final wet parameter conformity, sealed in small glass vials and autoclaved at 120°C for at least 15–20 minutes to effect sterilization. Advances in lathing technology and computer-controlled processing have led to the

Fig. 5.1 A laboratory using the labour-intensive method of lathe cutting to manufacture soft contact lenses.

development of semiautomatic systems whereby stacks of buttons are automatically fed into lathes; however, even this technology cannot match the mass-production capabilities of cast moulding.

Fig. 5.2 is a schematic flow diagram illustrating the process of manufacturing a soft contact lens using lathe-cutting technology.

The process of manufacturing rigid contact lenses by lathe cutting is very similar to the process described above – the key difference being that, with soft lens manufacture, the xerogel must eventually be hydrated and sterilized, whereas rigid lenses need only to be cut to their final shape and polished. Other notable manufacturing differences concerning materials of high gas permeability are tighter manufacturing tolerances and the requisite for more critical control of cutting and mounting temperatures in order to preserve their in vivo wetting properties. A pictorial account of this process of rigid contact lens manufacture, and an explanation of how toric lenses are made using lathe cutting, is given in Chapter 12.

SPIN CASTING

In this process, a convex 'male-shaped' stainless steel tool, or 'insert', is produced on a high-precision engineering lathe and lapped to provide an accurate surface that matches the dry dimensions of the proposed anterior surface of the contact lens. Modern non-ferrous materials are also suitable for producing the mould tool and these materials can be generated on 'nano-accurate' single point turning lathes. These lathes can cut mould tools to a surface finish that renders polishing unnecessary. The final surface shape of the master mould tool is verified using interferometry or other similar non-contact measuring methods. Any given tool is used to make hundreds of thousands of moulds.

The metal tool is impressed against heated liquid polypropylene or polyvinyl chloride (PVC), which then cools and sets to form a solid plastic concave female mould. A multiple number of metal tools (typically 8×–12×) is used to produce the same number of plastic moulds simultaneously. The moulding methods and tooling used must be very accurate in order to preserve

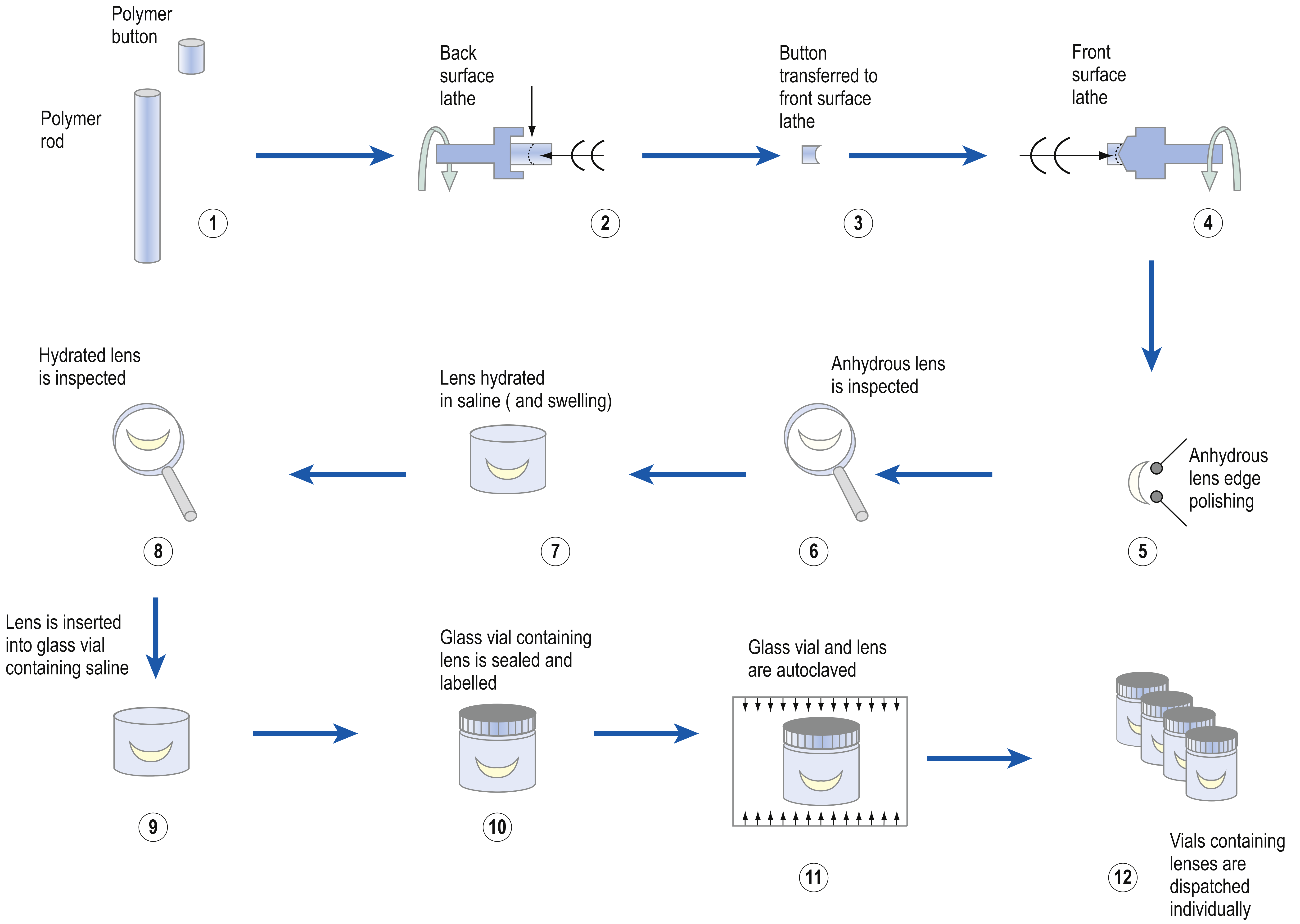
Polymer button
Polymer rod
①
Back surface lathe
②
Button transferred to front surface lathe
③
Front surface lathe
④
Hydrated lens is inspected
Lens hydrated in saline (and swelling)
Anhydrous lens is inspected
Anhydrous lens edge polishing
⑧
⑦
⑥
⑤
Lens is inserted into glass vial containing saline
Glass vial containing lens is sealed and labelled
Glass vial and lens are autoclaved
⑨
⑩
⑪
⑫
Vials containing lenses are dispatched individually

Fig. 5.2 The process of manufacturing a soft contact lens by lathe cutting. (1) The dry polymer is supplied as a rod or button. (2) A polymer button is placed on a lathe; the button spins and a diamond tool is advanced towards the button to generate the lens back surface. (3) The button is released from the back surface lathe. (4) The button is mounted on a front surface lathe with adhesive wax; the button spins and a diamond tool is advanced towards the button to generate the lens front surface. (5) The dry lens is removed from the lathe and the edges are polished. (6) The lens is inspected at 17× magnification. (7) The dry lens is placed in saline to hydrate the lens, which swells to its final soft lens form. (8) The hydrated soft lens is inspected at 10× magnification. (9) The soft lens is inserted into a glass vial containing saline. (10) The glass vial is sealed and labelled. (11) The sealed glass vial containing the lens is sterilized in an autoclave. (12) The individual glass vials are dispatched.

the concentricity of the resultant plastic part. Any moulding runout will create unwanted prism in the lens during the spinning process. This type of injection cast moulding is generally conducted in a controlled environment (usually to a class 100K level). It is imperative for a spin-cast manufacturing process to control the level of potential contaminants to a minimum as it is an open-moulding system.

The xerogel lens form is created by pouring liquid monomers into the concave moulds, which spin at a controlled rate about the central mould axis.

This spinning takes place in a controlled atmosphere of nitrogen or similar oxygen-deprived atmosphere (Fig. 5.3). This is necessary as the spin mould is an open system and thus exposes one surface of the lens (posterior) to air as it is being cured. Oxygen in air is a natural scavenger of the initiator and will ultimately inhibit the polymerization process.

The speed of rotation, combined with both the mould tool shape and monomer dose, ultimately determines the final lens parameters. The shape of the back surface is primarily governed by centrifugal force generated by the rate of spin of the mould, surface tension forces between the mould and polymer, and the effects of gravity. A greater speed of rotation of the mould will result in more polymer mass being shifted towards the lens periphery, and more negative lens power. Due to this system of manufacture, certain process controls such as monomer dosing must be more accurate than those found in full cast moulding of contact lenses.

As the mould spin rate stabilizes, ultraviolet radiation and / or heat is introduced to initiate polymerization. The lens is removed from the mould, and the mould is discarded. Certain spinning processes hydrate the lens in the original plastic mould and it is never removed. This process has been proven advantageous and cost-effective for the mass production of daily disposable lenses.

Other spinning systems still require that the edges of the lens are polished and that the lens be inspected, hydrated, re-inspected, packaged and autoclaved. Spin casting can produce a much higher output volume than lathe cutting, and in the latest systems can match the high volume of lenses that can be produced by cast moulding. The primary restriction of spin-cast manufacture lies in its inability to generate a fully formed edge from the posterior to anterior surface; however, sophisticated design modelling, combined with accurate tooling, has largely mitigated this limitation. The process of spin casting is illustrated in Fig. 5.4.

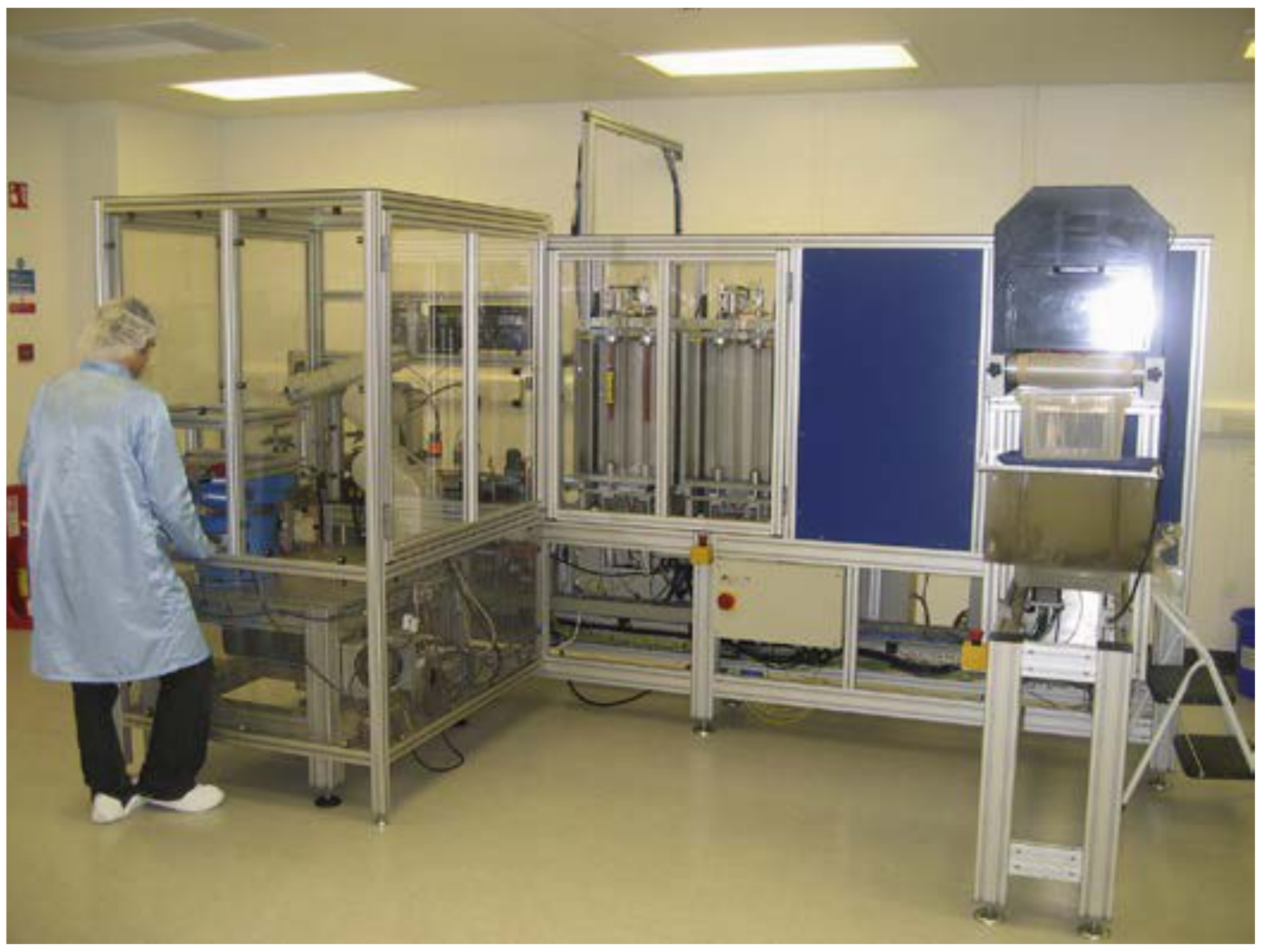

Fig. 5.3 A manufacturing line for spin casting soft contact lenses.

CAST MOULDING

Cast moulding has become the dominant technology in high-volume lens manufacture. As with spin casting, a series of highly polished steel tools is used to fabricate polypropylene moulds; however, matching male and female moulds are required for cast moulding. Again, modern non-ferrous materials are suitable for producing the mould tool and can be generated to extremely fine levels of accuracy and surface finish. These master tools are used to make hundreds of thousands of male and female moulds (Fig. 5.5).

The variations found in different manufacturing facilities around the world, however, attest to significant development in challenging this norm. Modern moulding machines can create reproducible results (a critical requirement for the high volume production of contact lenses, particularly daily disposable lenses) with higher numbers of tools. Some machines can successfully carry as many as 36 cavities (18 males and 18 females) in one mould base. Moulding parameters, tool accuracy, cooling and balancing are critical if this is to be successful. The manufacturer will seek a balance between output and accuracy with the moulding process.

Cast moulding generally takes place in a continuous, automated production line (Fig. 5.6). Monomer in liquid form is introduced into a concave female mould, which defines the shape of the lens front surface. An ultraviolet-transparent male mould is mated to the female mould and the two are clamped together in a carefully controlled environment.

The contact lens edge is formed when the two sides of the mould come together. There is considerable science and art in the control of the polymerization process and the pressure that is applied to the mould to form the lens. A crucial aspect of this process is to arrange for the excess polymer (so-called 'flash') to be squeezed out while leaving the edge intact.

Once the polymer is encapsulated in the mould, it is 'cured' – a process in which the assembled moulds are exposed to either UV light or thermal radiation, or a combination of both, to effect polymerization so as to form the dry contact lens. Most cast-moulding processes are designed so that when the dry lens is removed from the mould there is no need to polish the edge. The moulds are disassembled and discarded, and the lens that is released from the moulds – still in rigid form – is hydrated in saline.

Inspection is undertaken either manually (Fig. 5.7) or using automated video-based computer-controlled image analysis. Finally, the lens blister packs are sealed, labelled (Fig. 5.8), autoclaved, and packaged in boxes. Fig. 5.9 is a flow diagram of the cast moulding process.

It should be recognized that the above descriptions are highly simplified accounts of sophisticated engineering processes. Various manufacturers have introduced a number of unique variations, such as wet-state polymerization, the employment of reusable glass moulds (Hough, 1998), use of the male half of the mould for final lens packaging, and vertical production lines to optimize the use of costly floor space. Also, toric and bifocal lenses can be manufactured using either spin-casting or cast-moulding technology by engineering the master tools to contain the desired lens forms; these design elements will then be faithfully transposed to the moulds and then to the final lens.

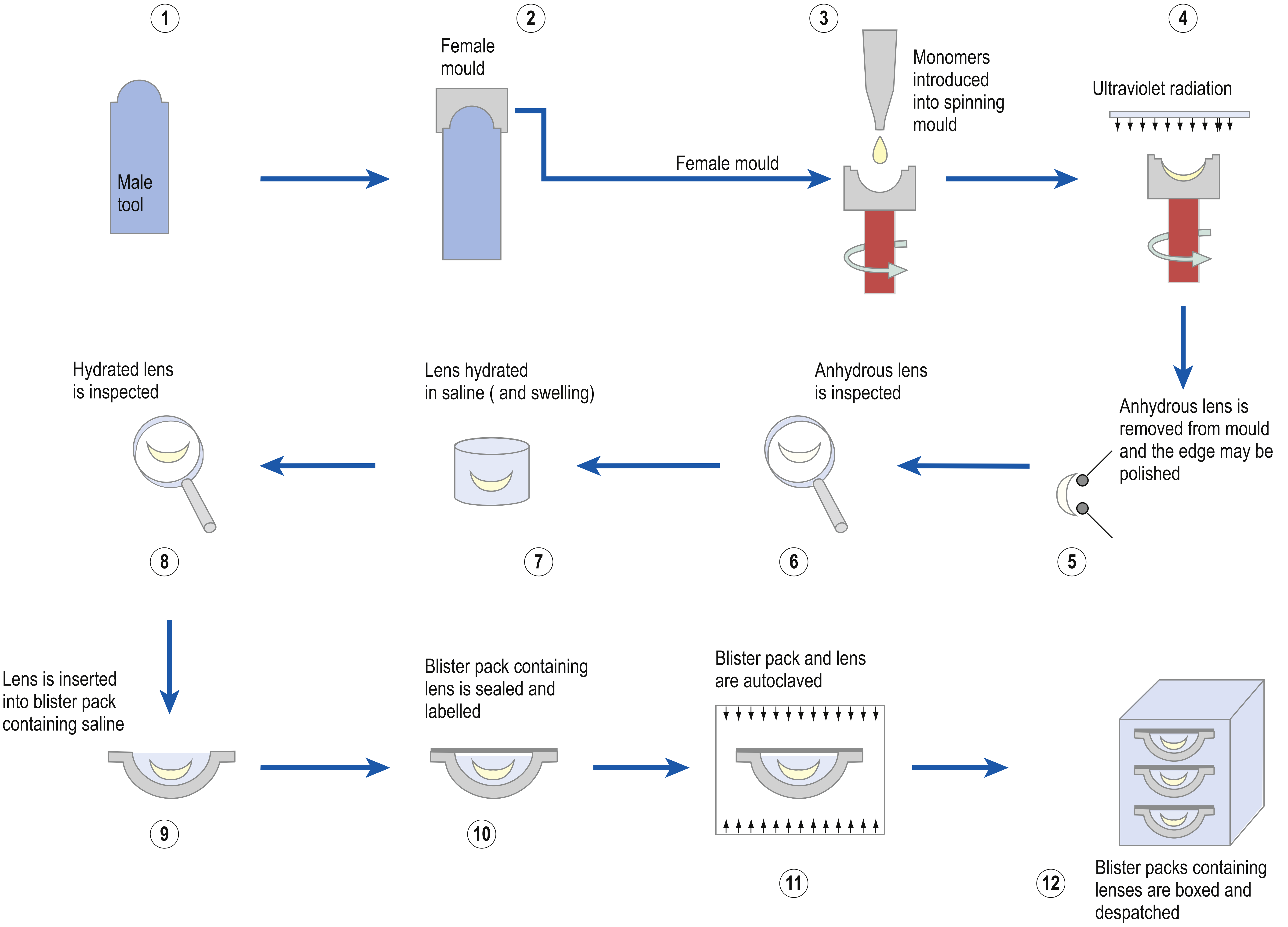
1
Male tool
2
Female mould
Female mould
3
Monomers introduced into spinning mould
4
Ultraviolet radiation
Anhydrous lens is removed from mould and the edge may be polished
5
Anhydrous lens is inspected
6
Lens hydrated in saline (and swelling)
7
Hydrated lens is inspected
8
Lens is inserted into blister pack containing saline
9
Blister pack containing lens is sealed and labelled
10
Blister pack and lens are autoclaved
11
12
Blister packs containing lenses are boxed and despatched

Fig. 5.4 The process of manufacturing a soft contact lens by spin casting. (1) A male tool is machined from stainless steel; the contour of the tool head will define the shape of the anterior lens surface. The same tool is used to make hundreds of thousands of moulds. (2) A female mould is made by pressing the male tool into molten polypropylene, which cools and sets. (3) The female mould is mounted, with the concavity facing upwards, in a spindle that spins about the lens axis, and liquid monomers are introduced into the spinning mould. (4) The monomers in the spinning mould are irradiated with ultraviolet light to initiate lens polymerization. (5) The dry lens is removed from the mould, the lens edge may be polished and the mould is discarded. (6) The edge of the dry lens is inspected at 10× magnification. (7) The dry lens is placed in saline, which hydrates the lens, causing it to swell to its final soft lens form. (8) The hydrated soft lens is inspected at 10× magnification. (9) The soft lens is inserted into a blister pack containing saline. (10) The blister pack is sealed with a special foil, and a label is stuck on to this. (11) The sealed blister pack containing the lens is sterilized in an autoclave. (12) The individual blister packs are inserted into packages, typically in multiples of either three or six lenses.

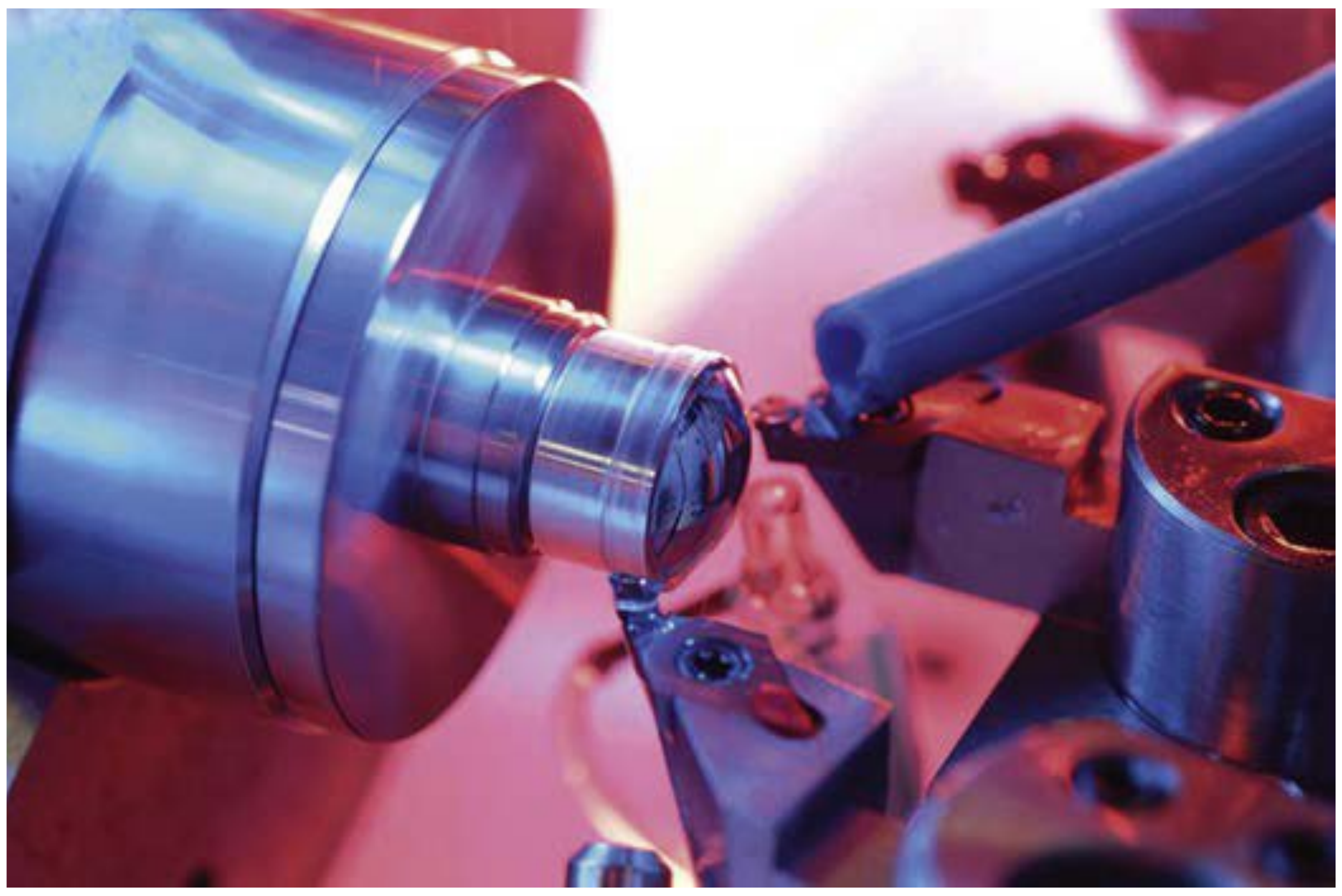

Fig. 5.5 Generating a metal master tool.

Fig. 5.6 A manufacturing laboratory for cast moulding soft contact lenses.

Fig. 5.7 An inspection laboratory for quality checking soft cast-moulded contact lenses.

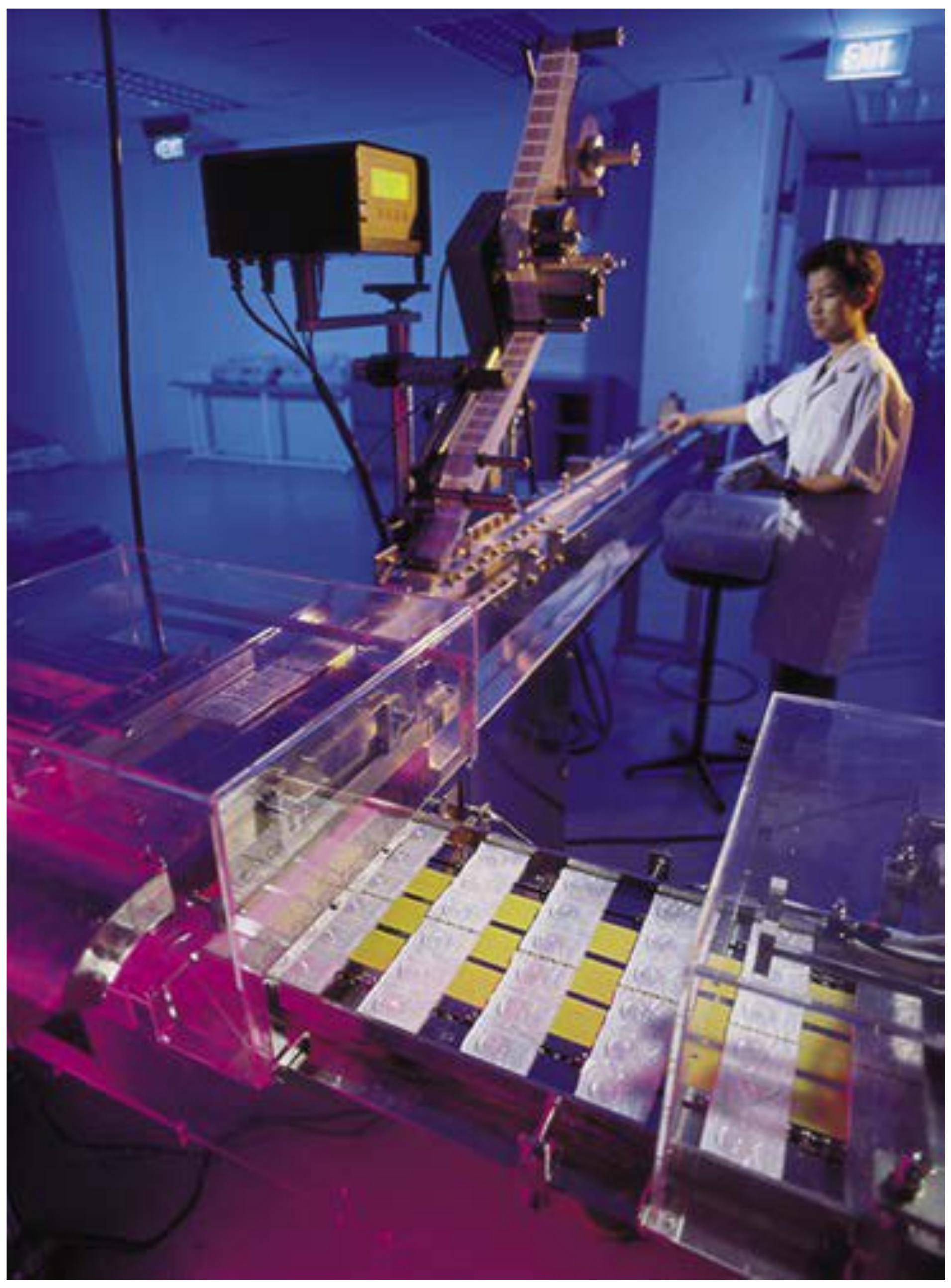

Fig. 5.8 A blister packing line for packing and labelling soft cast-moulded contact lenses.

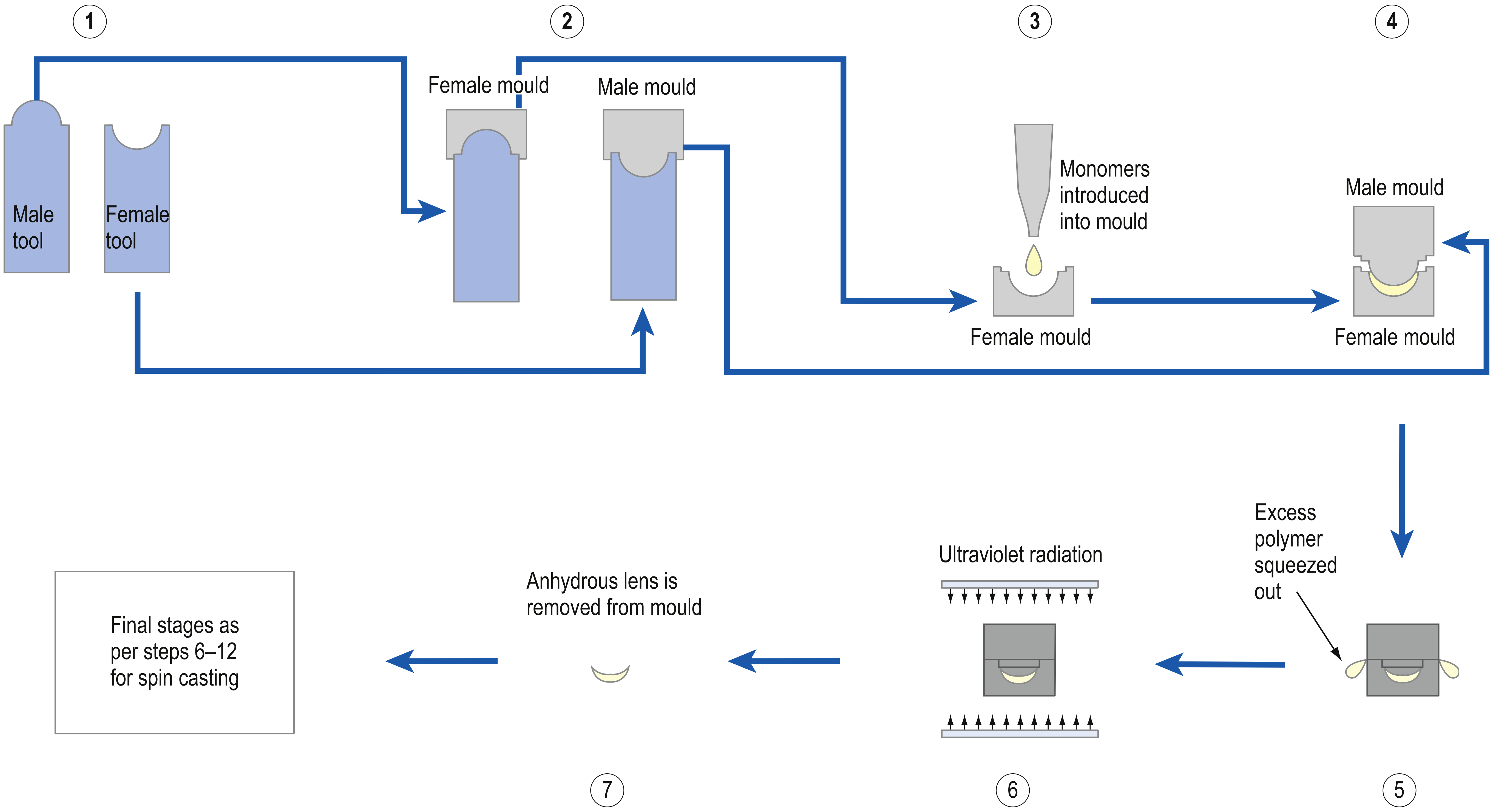
①
②
③
④
Male tool
Female tool
Female mould
Male mould
Monomers introduced into mould
Female mould
Male mould
Female mould
Excess polymer squeezed out
Ultraviolet radiation
Anhydrous lens is removed from mould
Final stages as per steps 6–12 for spin casting
⑦
⑥
⑤

Fig. 5.9 The process of manufacturing a soft contact lens by cast moulding. (1) Male and female tools are machined from stainless steel; the contour of the male tool head will define the shape of the anterior lens surface, and the contour of the female tool head will define the shape of the posterior lens surface. The same tools are used to make hundreds of thousands of moulds. (2) Male and female moulds are made by pressing the tools into molten polypropylene, which cools and sets. (3) The female mould is mounted in an accurate aligning fixture, with the concavity facing upwards, and liquid monomers are introduced into the concavity. (4) The male mould is registered over the female mould and the two moulds are clipped together. (5) Excess polymer is squeezed out from the sides of the mould. (6) The monomers inside the mould assembly are irradiated with ultraviolet light or thermal energy to initiate lens polymerization. (7) The dry lens is removed from the mould and the moulds are discarded. The final stages of lens production are essentially the same as for spin casting, which is illustrated in steps 6–12 in Fig. 5.4.

Reproducibility and Quality of Mass-produced Lenses

Practitioners who prescribe lenses, and patients who wear lenses, need to be assured of the reproducibility of lenses that have been manufactured using mass-production techniques. Young et al. (1999) determined the reproducibility of 24 lenses in three lens powers (−1.00 D, −3.00 D and −6.00 D) of eight common frequent replacement spherical soft contact lens types. They found that the mean power of all the lenses was higher than their labelled powers, although all were within the tolerance ranges. Reproducibility was observed to be worse for all lenses at higher powers. All but two lens types had mean diameters within tolerance. A slight reduction of optical quality at high powers was noted. Measures of back optic zone radius, centre thickness and overall diameter showed reasonably good repeatability.

In a similar study conducted on three brands of daily disposable contact lenses, Efron et al. (1999) found that 450 lenses of −3.00 D in power displayed an overall high degree of accuracy and reproducibility. They concluded that, with a single inconsequential exception, all measured parameters were found to fall well within clinically acceptable limits for providing wearers of these lenses with consistent vision and fit.

Efron and Veys (1992) examined the quality of three types of early-generation disposable lenses at 17× magnification using an Optimec JFC Contact Lens Analyzer. An overview of the observed defects revealed that they could be divided into two broad categories – edge defects and non-edge (body) defects (Fig. 5.10).

Each of these categories could be further divided into four subcategories, as follows:

EDGE DEFECTS

- Nick – small piece of lens material missing from lens edge.
- Tear – partial or full separation of lens material continuous with lens edge (Fig. 5.11).
- Roughness – uneven edge profile.
- Excess material or flash – lens mass or surplus material extending beyond lens circumference.

NON-EDGE (BODY) DEFECTS

- Split – partial or full separation of lens material that is not continuous with lens edge.
- Blemish – hazy, low-transparency region of lens, on lens surface or within lens.
- Eccentric optic zone – optic zone not concentric with lens perimeter.
- Multiple pieces – lens separated into sections.

Some lenses contained more than one defect, and a high prevalence of nicks, tears, roughness and blemishes was observed. At the time, other authors reported similar findings (Wodis et al., 1990; Holden et al., 1991; Lowther, 1991). These studies accorded a valuable service to the contact lens industry in the early 1990s as they focused attention on the importance of the quality of mass-produced lenses, especially edge quality. Advances in cast-moulding manufacturing technology over the past quarter of a century, fuelled by the attention drawn to the above issues, has led to a substantial overall improvement in lens quality.

At a microscopic, subclinical level, it can be observed that different manufacturing techniques can have a significant effect on the finished lens surface. Fine concentric rings can often be seen on the surface of soft lenses that have been manufactured by lathe cutting; these 'lathe marks' are often visible under high magnification using the slit-lamp biomicroscope. Using atomic force microscopy, Bhatia et al. (1997) observed that the surface of unused cast-moulded lenses varied from smooth to rough with surface features unique to the polymers and manufacturing process.

Maldonado-Codina and Efron (2005) investigated the impact of manufacturing method and material composition on the surface characteristics of five types of hydrogel contact lenses: three polyhydroxyethyl methacrylate (pHEMA) lenses, each manufactured by a different technique, namely, lathing, spin casting and cast moulding, a HEMA/methacrylic acid cast-moulded lens and a HEMA/glycerol methacrylate cast-moulded lens. Front and back lens surfaces were examined using scanning electron microscopy (SEM) and atomic force microscope (AFM). The surfaces of the lathed lenses were covered in lathing/polishing marks. In general, at a microscopic level, the anterior surface appeared rougher. All three cast-moulded lenses had more processing debris than did the

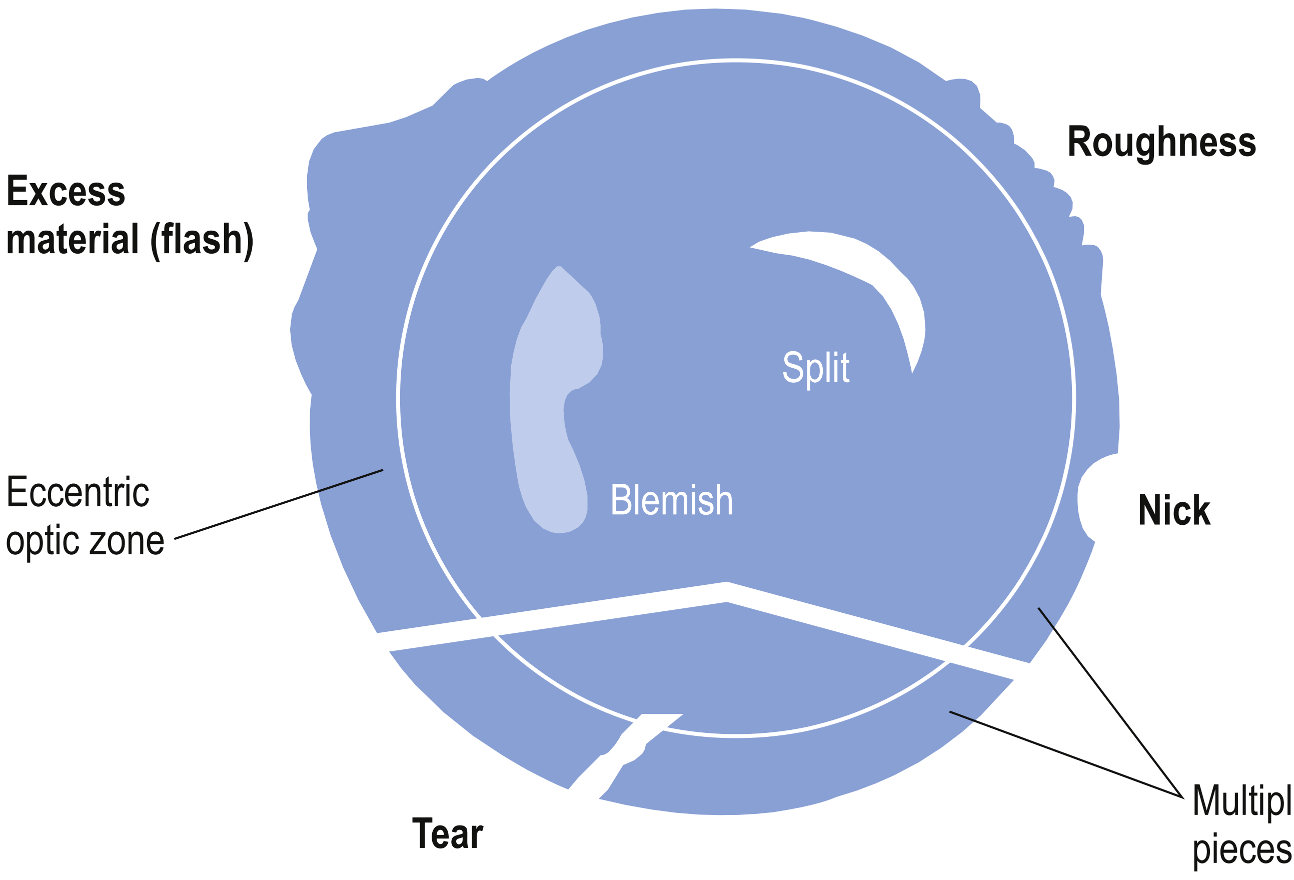

Fig. 5.10 System for classifying the types of defects that can be observed on contact lenses. Edge defects are indicated in bold font, and body defects in plain font.

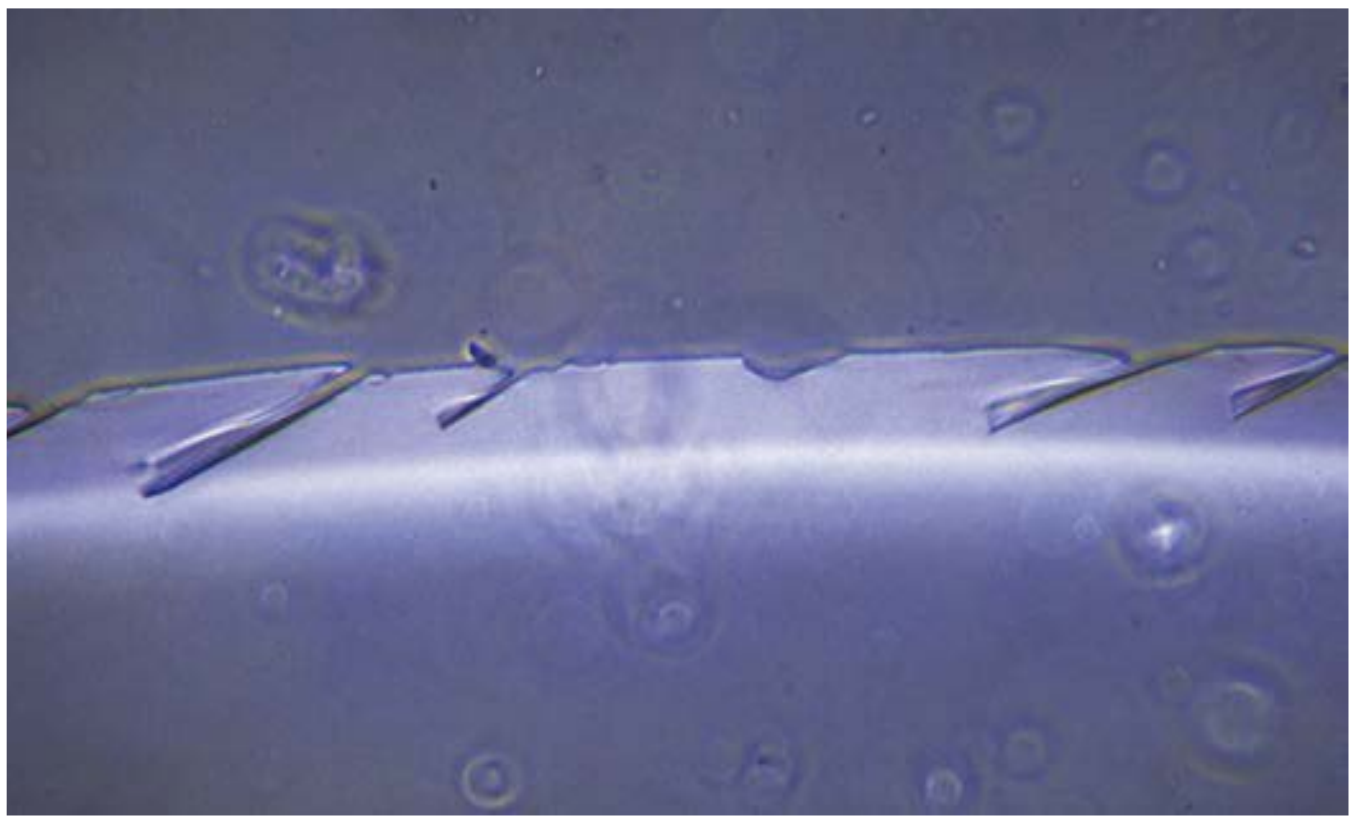

Fig. 5.11 Tears in the edge of a disposable soft lens observed at 100× magnification. Such edge defects are uncommon with modern cast-moulding technology.

lathed and spun-cast pHEMA lenses. Overall, the surfaces of the lathed lens were 'rougher' than those of the cast-moulded lens. Maldonado-Codina and Efron (2005) concluded that surface topographies of hydrogel contact lenses are dependent on method of manufacture. They also noted that cast-moulded lenses are associated with apparently 'stickier' surfaces, which may be indicative of surface degradation or cure-related issues during the manufacturing process.

Maldonado-Codina and Efron (2004) measured high- and low-contrast visual acuity, and the level of protein deposition, in patients wearing HEMA lenses made by three manufacturing methods. They found that spun-cast HEMA lenses deposited less protein than cast-moulded or lathed HEMA lenses; however, the differences in the amount of protein deposited did not affect visual function.

The impact of manufacturing method on pre-lens tear film of soft HEMA contact lenses was also investigated by Maldonado-Codina and Efron (2004). Manufacturing method was found to have only a minor effect on the quality and stability of the pre-lens tear film in HEMA lenses. The authors concluded that pre-lens tear film structure is likely to be more related to material and patient characteristics than to manufacturing method.

Occupational Safety in Lens Manufacture

As with all manufacturing processes, precautions must be put in place to ensure the personal safety of those working in contact lens manufacturing plants.

Lee et al. (2009) reported the case of a 36-year-old Chinese man who presented with a 4-month history of a work-related, recurrent, bilateral dermatitis affecting the tips of his fingers and thumbs after 9 months of work in a factory manufacturing disposable contact lenses. Clinical examination showed scaly, eczematous plaques limited to the left thumb, index, and middle fingertips as well as the right index and middle finger tips. Personal protective equipment included safety boots, latex gloves and goggles.

The manufacturing process of these contact lenses involves the moulding of polypropylene casts and the injection, spinning, and UV curing of liquid acrylic monomers. These processes are automated and enclosed. Hence, workers do not have direct contact with the chemicals. This worker, however, a technician involved in the servicing and maintenance of the manufacturing machines, was apparently exposed to the liquid monomers in the machines. The constituent monomers used in the contact lens manufacture were 2- hydroxyethyl methacrylate (2-HEMA), glycerol monomethacrylate (GMA) and ethyleneglycol dimethacrylate (EGDMA). Other substances handled included machine oil, acetone, and isopropyl alcohol.

Although acrylates are common sources of occupational hand dermatitis, acrylate sensitization from contact lens manufacturing is rarely seen.

The worker was using latex gloves, which protect poorly against acrylates, as acrylates penetrate over relatively short periods. He was moved to another section of the factory, where the acrylates had been cured and were not in monomer form; there was no further recurrence of his dermatitis.

This report highlights the sensitizing potential of acrylate monomers such as 2-HEMA and EGDMA in the manufacture of contact lenses, and the need for worker education and training to increase awareness and improve compliance with occupational hygiene precautions. It also highlights the importance of understanding the work processes so that appropriate recommendations can be made to the management to reduce the risk of dermatitis.

Conclusion

The three primary methods of manufacturing soft contact lenses are lathe cutting, spin casting and cast moulding. The technique of cast moulding has become the dominant form of soft contact lens manufacture because it is capable of producing sufficient quantities of high-quality lenses so as to meet the intense clinical demand for affordable planned replacement and disposable lens-wearing modalities. Practitioners can be reassured that modern soft lens-manufacturing techniques produce lenses of high quality and good reproducibility.

ACKNOWLEDGEMENTS

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Access the complete references list online at http://www.expertconsult.com.

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6

Soft Lens Optics

W NEIL CHARMAN

Introduction

Single-vision soft contact lenses have a number of optically attractive features. They centre well on the cornea with only small amounts of lateral movement and hence introduce little additional asymmetric aberration into the lens–eye system. The diameter of their optic zone normally exceeds that of the entrance pupil of the eye under all lighting conditions; thus, the 'haloes' around light sources that are observed at night following excimer refractive surgery or during wear of some rigid lenses are avoided. Their large overall diameter, greater than that of the cornea, ensures the absence of the discontinuities, flare and stray light effects that can arise with smaller-diameter rigid lenses in the peripheral visual field, which are due to refractive and scattering effects at the lens edges. Their refractive index (about 1.37–1.48) is quite close to that of the cornea, so that Fresnel reflection losses are comparable with those in the natural eye. They shape themselves so that their back surface conforms closely to the anterior surface of the cornea, thus minimizing fitting problems.

On the other hand, the tendency to drape to conform to the corneal surface and the consequent near-elimination of tear lens effects mean that, unlike rigid lenses, soft lenses cannot compensate for modest amounts of corneal astigmatism. Only by using a well-stabilized toric lens can the latter be corrected (see Chapter 9). Other possible disadvantages from the optical point of view include lens flexure and hydration variations, which, together with spatial non-uniformities in the thickness of any post-lens tear film, may result in on-eye power changes. This chapter is primarily concerned with such on-eye power changes and the interaction of the higher-order aberrations of the lens and the eye, insofar as they apply to the optic zone of spherical corrections.

On-eye Power Changes

Before being placed on the eye, the back vertex power of a soft lens is normally checked when the lens is at room temperature in a fully hydrated state (see Chapter 7). As has already been noted, when the soft lens is worn, its inherent flexibility allows it to 'drape', so that the shape of the posterior surface approximates closely to that of the anterior cornea. While this greatly simplifies fitting, any associated changes in the curvatures of the lens surfaces and lens thickness may result in the on-eye power of the lens differing slightly from that measured off-eye.

Although draping implies that the tear lens between the contact lens and the cornea ought to have zero power, this may not always be the case. Wechsler et al. (1979) found no evidence for a significant tear lens, and several subsequent authors agreed with this result (Chaston and Fatt, 1980; Holden and Zantos, 1981; Plainis and Charman, 1998). However, Weissman and Zisman (1979) and Michaels and Weissman (1982) suggested that a tear lens about 10 µl in volume may sometimes exist and contribute about −0.15 D of power to the combined lens–eye system. Weissman and Gardner (1984) went on to propose that, although low-minus lenses may entrap only a small volume of tears (about 5.5 µl), thicker, low-plus lenses may entrap a greater volume (about 9.5 µl l), giving a correspondingly greater tear lens effect (up to −2.00 D).

Changes in hydration, which are a function of the lens design and material (Andrasko and Schoessler, 1980; Andrasko, 1983; Brennan and Efron, 1987), the wearer, the visual task and the environmental conditions (Efron et al., 1987; Brennan et al., 1988) will affect the refractive index and geometry of any soft lens, and hence its power. Typically, hydration may fall by around 5–10% after the first hour of lens wear (Wechsler et al., 1982; Andrasko, 1983; Efron and Morgan, 1999). Thinner lenses reach equilibrium after about 5 minutes, whereas thicker, high-power positive lenses may continue to dehydrate for 30 minutes or more after insertion. Effects appear to be material dependent (Brennan and Efron, 1987); in particular, high-water-content lenses dehydrate more and reach equilibrium sooner than lower-water-content lenses of comparable thickness. There is a strong suggestion that greater dehydration may occur during near work, due to reduced blinking, and when atmospheric humidity is low. Water loss can occur by several pathways, including evaporation into the atmosphere, drainage into the nasolacrimal system and, possibly, absorption into the conjunctival capillaries.

As the corneal temperature is around 32–35°C (Efron et al., 1989), while the room temperature is normally about 20°C, there is a change in temperature when the lens is put on the eye; this affects all the lens parameters (Fatt and Chaston, 1980a, b; Purslow et al., 2005) including hydration and refractive index. The measurements made on a variety of soft lens materials by Fatt and Chaston (1980b), however, suggest that the maximum increase in $(n_L - 1)$, where n_L is the lens refractive index, is only about 1 part in 40 for a temperature rise of 14°C, so that the associated power change in a lens of this material would be only about 0.25 D for a ±10 D lens.

Many authors have attempted to develop either theoretical or empirical models to allow overall on-eye power changes to be predicted (Ford and Stone, 1997; Patel et al., 1998; Plainis and Charman, 1998). Among the more mathematically sophisticated models of flexure alone are those based on the concept that the flexed lens always retains constant volume (Bennett, 1976) or that the arc length of the back optic zone of the lens remains constant (Holden et al., 1976). Experimental studies, whose results include the effects of all the factors mentioned, not just those of flexure, agree in indicating that any power changes are small for negative lenses but that larger, clinically significant changes, which increase with the lens power, occur for positive lenses.

This can be seen in Fig. 6.1, which compares a smooth continuous curve derived from best fits to a substantial body of experimental data by Holden et al. (1976), with other experimental data obtained by Plainis and Charman (1998) and Kollbaum et al. (2013). Also shown (dashed) is a curve based on the empirical equation proposed by Weissman (1984), that is:

$$\Delta r_1/\Delta r_2 = 1 - 0.05F$$

where Δr_1 and Δr_2 are the on-eye changes in the front and back surface radii of the contact lens and F is the unflexed back vertex power. For the purpose of Fig. 6.1 it has been assumed that the initial value of r_2 is 0.8 mm flatter than the corneal radius of 7.8 mm, and that the lens index is 1.43. It can be seen that, although there is reasonable agreement, to within about 0.25 D, between the formula's predictions for corrections up to about ±6 D, those for high-powered corrections are less consistent.

Dietze and Cox (2003) interpret such results in a different way. They suggest that the paraxial power of contemporary thin, disposable, soft lenses does not change when the lens is placed on the eye, and that any small apparent discrepancies in the expected subjective correcting effect are associated with the spherical aberration of the lens and eye. This would be expected to shift the optimal focus away from the paraxial value towards the marginal focus in a way that depended upon the pupil diameter and the sign and magnitude of the aberration. This view has, however, been challenged by some later work (Kollbaum et al., 2013), which indicates that although the off-eye powers generally agree with manufacturer labelling, small on-eye changes occur in both the paraxial spherical power and the spherical aberration of soft lenses. The exact effects vary in an unpredictable way with the details of the materials and lens design used by different manufacturers. In general, the results of this study are broadly in line with those of earlier authors and show that the largest on-eye changes occur for higher-powered positive lenses, which lose power (see Fig. 6.1).

It should be mentioned that unusually thick (up to 0.6 mm) soft lenses have occasionally been suggested for the correction of keratoconus (Kaufman et al., 1970; Koliopoulos and Tragakis, 1981; Campbell and Caroline, 1995). These show less draping during wear and might be expected to be accompanied by substantial tear lens effects and effective on-eye power changes.

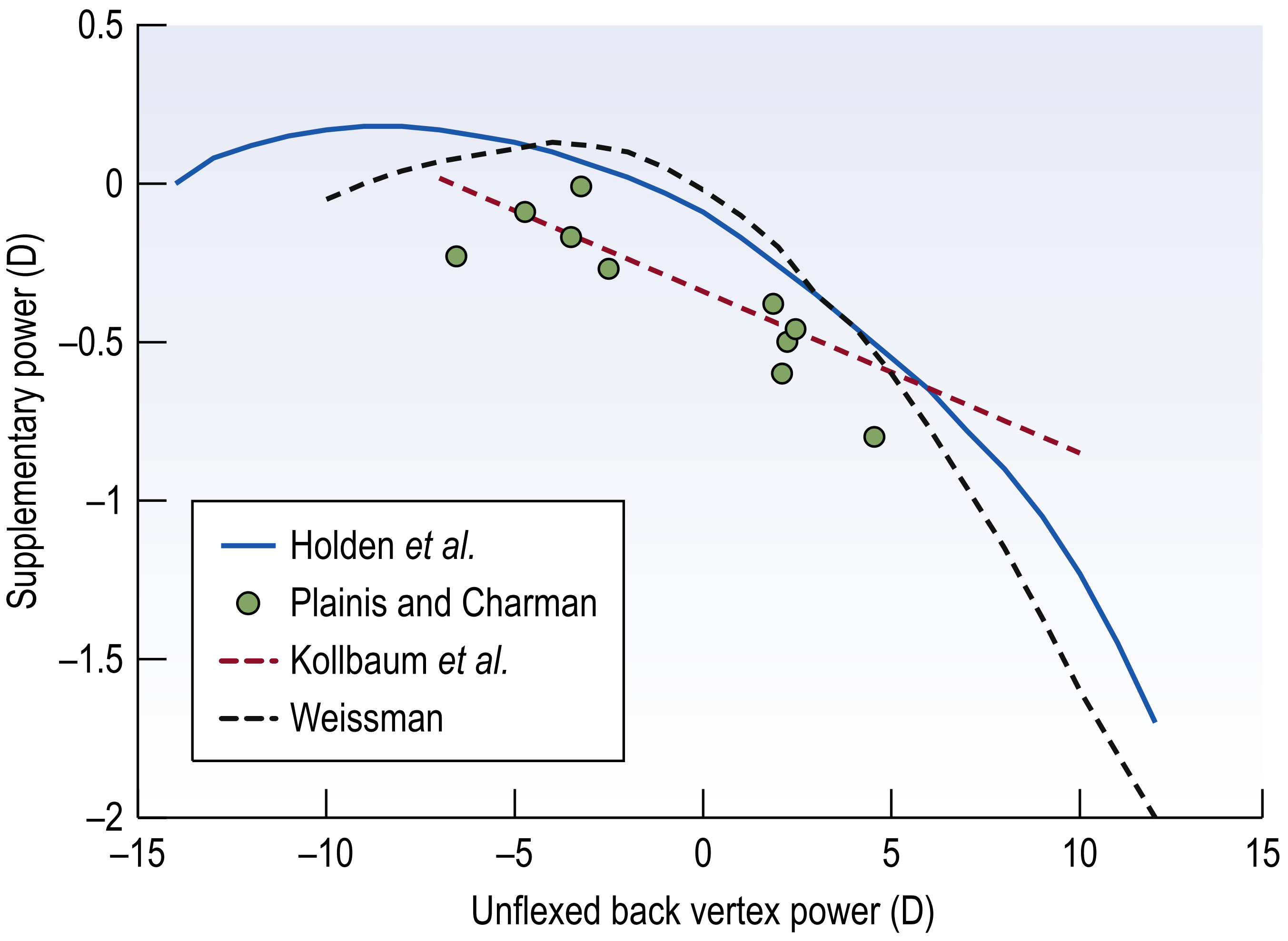

Fig. 6.1 Supplemental lens power (i.e. difference between on-eye power and in vitro power) as a function of in vitro power. (The smooth curves are from Holden et al. (1976; blue continuous line), Weissman (1984; black dashed line) and Kollbaum et al. (2013, red dashed line); the green dot symbols are experimental data obtained by Plainis and Charman (1998).)

At the present time neither modelling nor experimental data provide fully convincing predictions for on-eye power changes. All the earlier models involve inadequately justified assumptions and it is probable that additional factors such as material, lens design, fitting philosophy, patient tear flow and lens–lid interactions also influence the results occurring in practice. It may be that the greater thickness of the first generation of soft lenses unduly influenced the early results. Although predictions based on Fig. 6.1 should give a general guide to the magnitude of the on-eye power changes to be expected, for practical work it still seems more sensible to follow the conventional approach of trial lens fitting, as after suitable equilibration the trial lens will display on-eye effects similar to those of the ordered lens of the same design and power (Efron, 1991).

Aberration

Westheimer (1961) pointed out that, for foveal vision and well-centred, rotationally symmetric contact lenses having steeply curved surfaces, the classical lens aberration of greatest potential importance would be spherical aberration, in which the power of the contact lens varies with distance from its axis. This is in contrast to spectacle lenses where, as the eye moves with respect to the lens, oblique astigmatism, distortion and field curvature are all introduced whenever the visual axis moves away from the optical centre of the lens. Indeed, spherical aberration is of little importance in spectacle lenses, whereas control of the off-axis aberrations is a major design aim. As for primary spherical aberration the wavefront aberration varies with the fourth power of the radius in the pupil and the change in zonal power with the square of the radius, the greatest optical impact of spherical aberration is likely to occur when the pupil diameter is large, that is, under mesopic and scotopic conditions.

With the exception of diffractive lenses for presbyopes (see Chapter 23), longitudinal chromatic aberration is normally of negligible importance in either spectacle or contact lens design, as any contribution from the correcting lens is much smaller than that of the eye itself (see Chapter 3). Although transverse chromatic aberration associated with prismatic effects during oblique viewing is of great significance in relation to spectacle lens materials and their dispersion, it plays little role in relation to well-centred contact lenses.

Early work in this area concentrated on exploration of the benefits of aspheric lens surfaces in reducing the spherical aberration of the contact lens in isolation (Bauer and Lechner, 1979; Bauer, 1980). More recently, it has been realized that what matters is the combined aberration of the lens–eye system and that a contact lens with minimal spherical aberration does not necessarily lead to the best visual performance (Campbell, 1981). In principle, ideally the aberration of the lens should balance that of the eye, so that the combined system has minimal aberration (Fig. 6.2).

It is clear that, if any series of aspheric lenses designed to have a fixed level of spherical aberration for all lens powers is to offer useful improvements in the vision of patients by compensating for the eye's own spherical aberration, several conditions must be fulfilled:

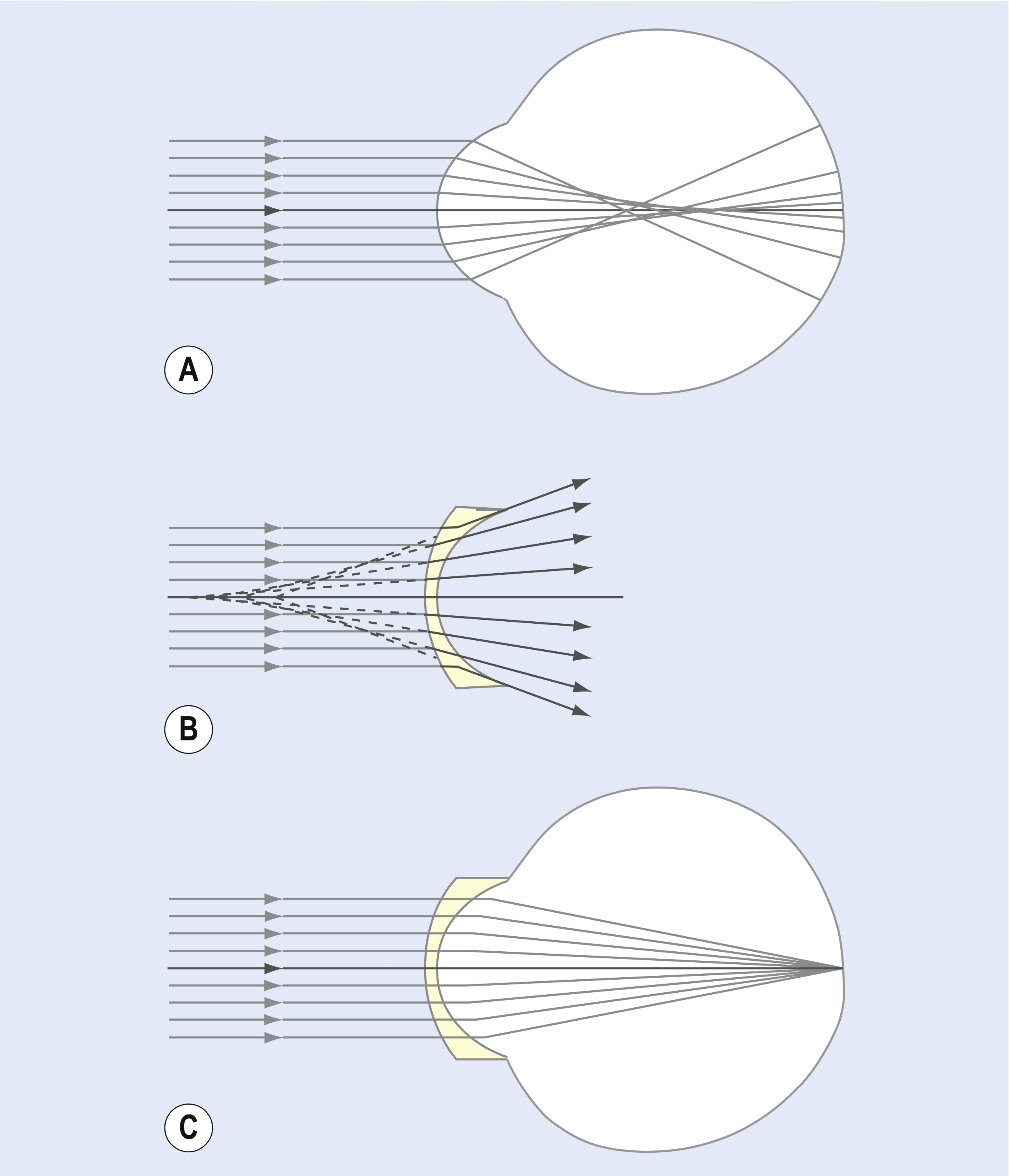

Fig. 6.2 Concept of balancing the positive spherical aberration of a myopic eye with a negative lens having negative spherical aberration. (A) Eye alone; (B) lens alone; (C) combined corrected lens–eye system.

- The spherical aberration of the eye should be consistent from patient to patient.
- Spherical aberration should be the major ocular aberration, so that its neutralization produces a substantial reduction in root mean square (RMS) wavefront error.
- The on-eye spherical aberration introduced by the lenses should not differ from the off-eye aberration due to flexure or other factors, or if it does, it should vary in a systematic, predictable way.
- Lens wear should not induce any change in the ocular aberrations, for example through corneal warpage.
- Any decentration of the aspheric contact lens with respect to the axis of the eye should not itself introduce significant aberration.
- The neural components of the visual system should be capable of appreciating any benefits in optical image quality that correction might provide.

Although various early attempts were made to assess the impact on visual performance of soft lenses designed to have different levels of spherical aberration (Cox, 1990; Cox and Holden, 1990; Chateau et al., 1998; De Brabander et al., 1998), they produced somewhat mixed results, with some patients showing improvements, some no change and others a loss in visual performance. Under photopic conditions, with relatively small pupils, mean high- and low-contrast visual acuities produced with spherical and aspherical versions of the same lens showed no significant differences (Vaz and Gundel, 2003). Chateau et al. (1998) were, however, able to demonstrate that if the aberration of the lens was systematically varied then mesopic contrast sensitivity at 12 c/° passed through a peak for each patient: the optimal spherical aberration of the correcting lens tended to become more negative with age. Two groups of subjects aged between 20 and 45 years were used; one consisted of emmetropes and the other of myopes with corrections between −5.00 and −10.00 D. The range of lenses used was designed to display varying amounts of primary spherical aberration of the form:

$$P(r) = P_0 + Ar^2$$

where P_0 is the paraxial power, P(r) is the power at a distance r mm from the lens axis and A is a constant (D/mm^2). The values of A used ranged from −0.27 to +0.19 D/mm^2. For comparison, the values of A can be converted to the Zernike coefficient C_4^0 used to describe primary spherical aberration (see Chapter 3), for any pupil radius, R, by substitution in the equation:

$$C_4^0 = \left(AR^4\right) / \left(24\sqrt{5}\right)$$

Use of the parameter A to describe the spherical aberration has the advantage that it is independent of pupil diameter. Under the conditions of the visual measurements of Chateau et al. (1998), pupil diameters were typically around 6 mm.

Fig. 6.3A gives examples of the way in which the contrast sensitivity for individual subjects varied with the value of A, whereas Fig. 6.3B plots the variation in the value of A for optimal contrast sensitivity, A_{OPT}, against the age of the subjects in the emmetropic and myopic groups.

It appears that A_{OPT} becomes more negative with age, with the value always being more negative for myopes at any age. In subjects of all ages, the average value of A_{OPT} was −0.16 D/mm^2 in myopes and −0.054 D/mm^2 in emmetropes. It is of interest that these values are similar in magnitude but of opposite sign to the mean values of ocular spherical aberration of about +0.05 D/mm^2 found by Charman and Walsh (1985) or +0.07 D/mm^2 found by Radhakrishnan and Charman (2007) as a result of averaging available ocular wavefront aberration data across all meridians from various studies. This suggests that best visual performance may indeed involve a balance between lens and ocular aberration.

Unfortunately, interpretation of these earlier studies was hampered by the lack of information on the ocular aberrations of the individual subjects. Such information would have allowed each subject's visual results to be interpreted in terms of the combination of their ocular aberration with that of the lens. In recent years, the growing availability of effective aberrometers capable of rapidly estimating a patient's ocular aberration under clinical conditions has transformed this situation. As a result, a much clearer picture of the possible benefits of lenses designed to have a specific level of spherical aberration can now be obtained (Efron et al., 2008).

Summarizing this recent work in relation to the conditions discussed earlier:

- As outlined in Chapter 3, individual eyes show substantial variation in their levels of spherical aberration and in their overall higher-order aberrations. Although Chateau et al. (1998) appeared to find differences between myopes and emmetropes, the consensus view is now that mean spherical aberration does not seem to change systematically with refractive error (Fig. 6.4A). However, it does change with age, the mean value becoming progressively more positive (Fig. 6.4B; Salmon and van de Pol, 2006). This evidently explains the finding of Chateau et al. (1998) that the optimal aberration of the correcting contact lens became more negative with age. At any particular age there is a wide spread in the individual levels of spherical aberration

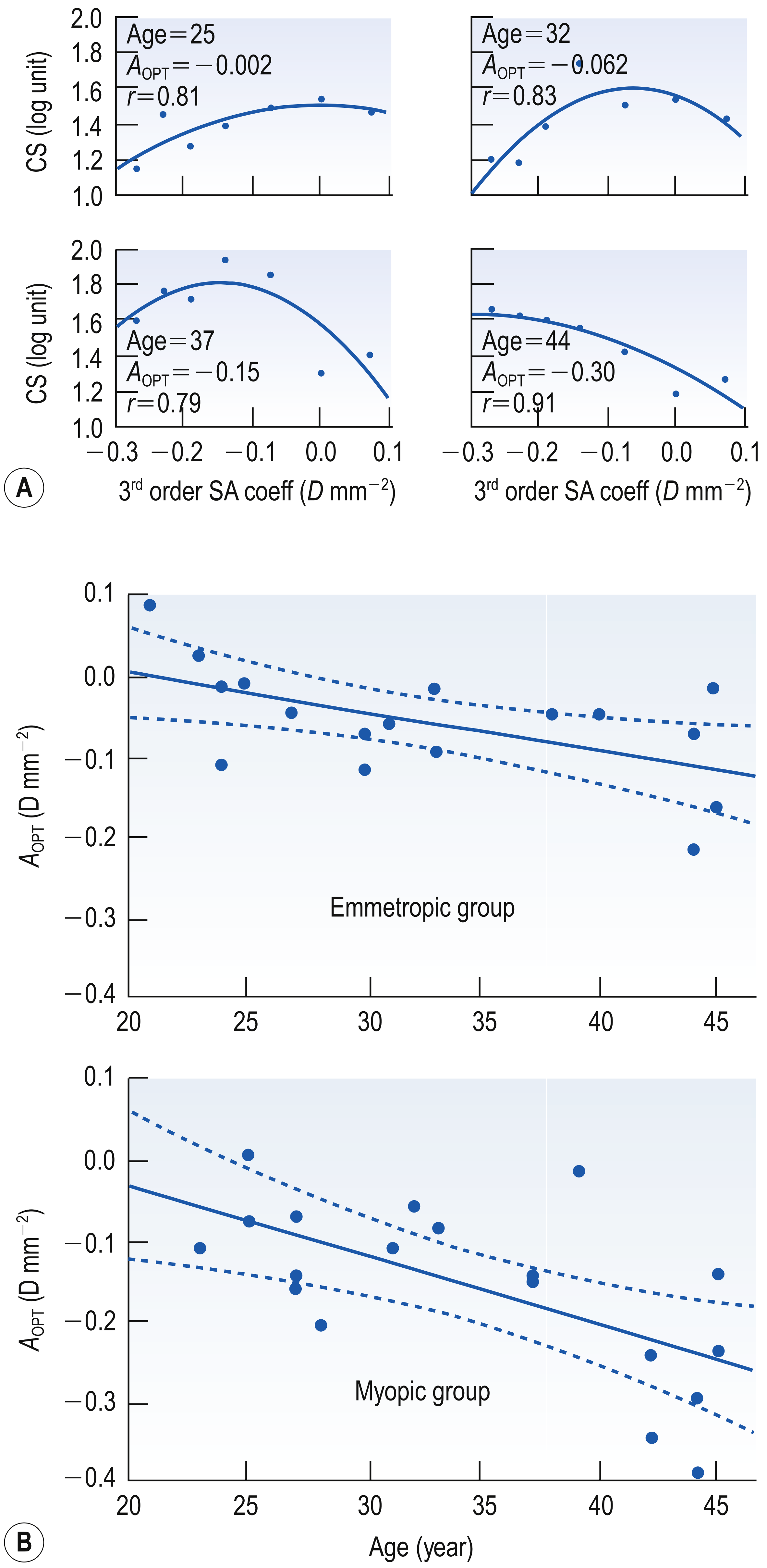

Fig. 6.3 (A) Contrast sensitivity (CS) at 12 c/° for four myopes corrected by soft lenses having different amounts of spherical aberration (SA), as specified by the third-order coefficient A. (B) Variation in the value of the optimal SA coefficient A_{OPT} for the correcting soft lens, as a function of age for emmetropic and myopic subjects. (Adapted from Chateau, N., Blanchard, A. & Baude, D. (1998). Influence of myopia and aging on the optimal spherical aberration of soft contact lenses. J. Opt. Soc. Am. A, 15, 2589–2596.)

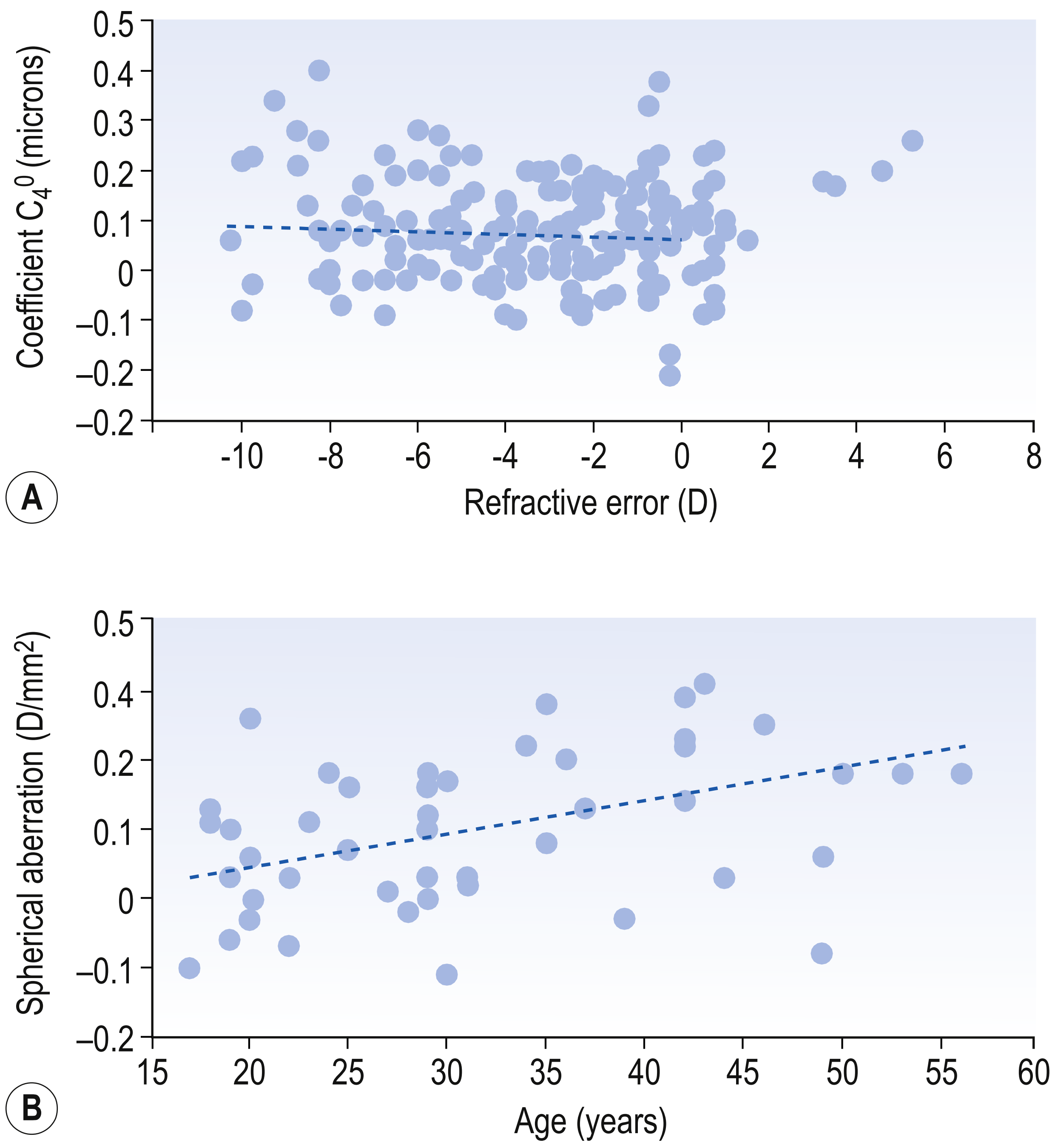

Fig. 6.4 (A) Root mean square primary spherical aberration, C_4^0, for a 6 mm pupil as a function of refractive error. (B) Primary spherical aberration, expressed in D/mm^2, for a 4.5 mm pupil as a function of age. In both plots right-eye data are shown. ((A) Adapted from Cheng, X., Bradley, A., Hong, X. & Thibos, L. N. (2003). Relationship between refractive error and monochromatic aberrations of the eye. Optom. Vis. Sci., 80, 43–49. (B) Adapted from Radhakrishnan, H. & Charman, W. N. (2007). Age-related changes in ocular aberrations with accommodation. J. Vis.,7, 1–21.)

(Fig. 6.4B; see also Chapter 3). No aspheric lens series with a fixed level of spherical aberration can then correct the spherical aberration of all patients. Although negative spherical aberration in the contact lens may benefit the majority of patents, after 'correction' the minority of younger eyes with negative aberration will have that level increased.

- Even if spherical aberration is corrected, substantial levels of other higher-order wavefront aberrations remain, as well as additional blur due to chromatic aberration and residual spherocylindrical refractive errors. If, for example, we take RMS wavefront aberration values for a 6 mm pupil diameter from the meta-analysis by Salmon and van de Pol (2006), the mean RMS in the fourth-order Zernike spherical aberration mode, Z_4^0, is 0.128 μm, in comparison with a total RMS aberration (third- to sixth-order) of 0.327 μm. Thus eliminating the spherical aberration would reduce the total RMS only to 0.301 μm, a relatively small improvement. For comparison, for this pupil diameter, an RMS wavefront error of 0.327 μm corresponds to an equivalent spherical defocus of about 0.25 D, which is about the level of reliability for clinical refraction techniques. In fact, as a generalization in soft lens work, it is often assumed that astigmatism needs to be corrected only when it exceeds 0.75 D, so that RMS wavefront errors due to uncorrected residual spherocylindrical errors often exceed those due to higher-order aberrations.
- It appears that the on-eye spherical aberration of thin soft contact lenses is similar but not identical to that found off-eye. Changes due to lens flexure, change in hydration, or post-lens tear film effects are small (Lopez-Gil et al., 2002; Dietze and Cox, 2003) but detectable, with the effective spherical aberration being reduced for higher-powered positive lenses (Kollbaum et al., 2013). Comparative studies in which the same subjects wore either standard soft or rigid gas-permeable contact lenses suggest that levels of total lens–eye wavefront aberration are generally lower with rigid lenses (Hong et al., 2001; Lu et al., 2003).
- Hydrogel lenses can undoubtedly, over time, cause marked corneal warpage and consequently changes in aberration (Schornack, 2003) in a minority of patients. As yet, the

question of whether more subtle levels of change occur in the majority of patients or with different lens materials remains to be explored.

- If an aspheric lens with significant levels of spherical aberration decentres, it will introduce coma (Dietze and Cox, 2004). It may, however, be possible to modify aspheric design to minimize the aberrations associated with decentration (Suzaki et al., 2007).
- The greatest optical improvements associated with correction of any form of monochromatic wavefront aberration are likely to be obtained when the pupil is large – that is, under natural mesopic and scotopic conditions. However, under such conditions, much of the observed degradation of spatial vision is caused by neural rather than optical factors. Thus even an ideal correction can improve visual performance to only a limited extent; such improvement is likely to be primarily in contrast sensitivity rather than high-contrast acuity (Charman and Chateau, 2003).

Overall, then, any claim that all normal patients would benefit markedly from an aspheric lens series with some fixed 'average' level of spherical aberration, compared with standard spherical lenses, is unlikely to be valid. This does not mean of course that the vision of specific individual patients, particularly those with unusually high levels of aberration, might not be usefully improved by some form of customized correction. The improvements in individual mesopic contrast sensitivity given by selecting the optimal lenticular spherical aberration in Fig. 6.3 illustrate this, although the improvement in contrast sensitivity over that for a lens with zero spherical aberration rarely exceeds about 0.2 log units (1.6×).

It seems likely that, in future, aberrometry will be a standard procedure in many clinical practices, since relatively low-cost, multirole instruments capable of aberrometry, topography and autorefraction are becoming increasingly available. As discussed, true customization of lenses to correct individual aberrations raises a number of problems. It may be that aberrometry followed by the selection of a suitable lens from a commercial series with several levels of spherical aberration for each paraxial power might allow practitioners to offer useful improvements in vision to at least some patients, particularly at mesopic levels where the pupil is large. This, however, demands larger lens inventories and perhaps a better solution may be simply to minimize any possible increase in aberration by making the contact lens have zero spherical aberration, rather than some average level of spherical aberration, which may increase the overall aberration when worn by some individuals (Kollbaum and Bradley, 2007).

As discussed briefly in Chapter 3, there is, in fact, continuing scientific and commercial interest in the possibility of fully customized soft contact lens corrections, particularly for those patients having high levels of ocular aberration. The optical thickness of the lens would be varied across its area in such a way as to compensate for all the higher-order aberrations of the eye, not just the spherical aberration. Although the required lenses lack rotational symmetry, their production by suitable excimer laser or asymmetric lathe-cutting techniques has already been successfully demonstrated (Lopez-Gil et al., 2002; Chernyak and Campbell, 2003; Jeong et al., 2005). The major problem is, however, that to be effective, any wavefront-correcting lens must undergo minimal rotation or translation on the eye (Bara et al., 2000; Guirao et al., 2001). The tolerances get smaller as the pupil diameter increases. Bara et al. (2000) suggest that, for a 6.5 mm pupil, permissible limits to rotation and translation are about 10° and 0.5 mm, respectively. The tolerances are larger for abnormal eyes, such as those of keratoconics (De Brabander et al., 2003; Jinabhai et al., 2012).

Preliminary trials with customized soft contact lenses suggest that first-generation customized lenses can match the acuity achieved with their habitual rigid lens correction (Marsack et al., 2008). No useful gains have been found for normal or post-penetrating keratoplasty patients, perhaps because of the difficulties in maintaining lens registration with the eye (Lopez-Gil et al., 2003; Sabesan et al., 2007). Nevertheless, this is an area where rapid developments may be expected to occur within the next few years.

In addition to their impact on axial refraction and aberrations, soft lenses affect refraction and aberration in the peripheral field (Shen et al., 2010; Shen and Thibos, 2011). This may be of significance if it is confirmed that imagery in the periphery of the younger eye influences the development of myopia (Smith, 2011).

Conclusion

The advent of clinical aberrometers is leading to rapid progress in our understanding of the way in which the optical design of soft contact lenses interacts with the second-order spherocylindrical refractive error and higher-order aberrations of the eye. At present it appears that, for photopic vision, making proper allowance for the possibility of on-eye power change is more important than concern about correcting aberration. Aspheric lens series offering a fixed 'average' level of spherical aberration appear to offer little general optical advantage over conventional designs with spherical surfaces. However, the availability of aberrometry, combined with aspheric lenses with different levels of spherical aberration, could allow a near-optimal lens to be offered to each patient and hence yield useful visual benefits under mesopic conditions if the lens remains well centred. Fully customized lenses based on aberrometric measurements may be particularly useful for keratoconic and other eyes with unusually high levels of aberration.

Access the complete references list online at http://www.expertconsult.com.

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7

Soft Lens Measurement

KLAUS EHRMANN

Introduction

The vast majority of soft contact lenses are today mass produced by a double-sided moulding process (see Chapter 5). Using such a method of manufacture ensures relatively consistent quality, eliminating the need to measure every lens that comes out of production. This standardization also makes it easier for manufacturers to meet regulatory requirements, and for practitioners and patients to have confidence that every lens that goes on eye is of good quality and correct power. Although this reduces the need for the contact lens fitter and dispenser to measure key lens parameters, manufacturers need to be even more diligent with their measurement methods, not only to ensure good product quality, but also to increase manufacturing productivity and gain the trust of practitioners and consumers.

The assiduous practitioner might still prefer to carry out basic lens measurements when investigating and seeking to resolve cases of unsatisfactory lens fit, poor comfort, or reduced visual performance.

Contact lens researchers also have a strong interest in lens metrology. Within the diverse range of research areas comprising biological science, clinical research and optical engineering, each group has specific requirements in measuring aspects of lens geometry, optical and material properties with great precision and accuracy.

To cater for these various applications and demands, a wide range of equipment has been developed over the years. In general, the required level of instrument sophistication and accuracy depends on the user group and increases from practitioners to manufacturers to researchers. A good reference guide on measurement methods, procedures and tolerances is the four-part ISO 18369 (International Organization for Standardization [ISO], 2006a, b, c, d) and its close US equivalent ANSI Z80.20 (Standard, 2010). These standards are of critical importance for manufacturers in demonstrating the safety and efficacy of their products; they are also a good reference guide for practitioners and researchers. The four parts of ISO 18369 cover:

Part 1: Vocabulary, classification system and recommendations for labelling specifications
Part 2: Tolerances
Part 3: Measurement methods
Part 4: Physiochemical properties of contact lens materials.

The tolerances as specified in ISO 18369 are listed in Appendix B.

It is in the nature of all hydrogel materials that they dehydrate quickly when removed from their aqueous environment. Exposure to air changes all physical and geometrical properties of the lens. Particular care is therefore required when making measurements in air to minimize these changes. Alternatively, most measurements can be performed in a wet cell, whereby the lens remains immersed in a saline solution. Even then, the pH and osmolality of the solution need to fall within narrow ranges as specified in ISO 18369-3 to ensure that correct water content and physical dimensions are maintained.

The key optical, material and geometrical parameters of interest are:

- Optical parameters
  - Power and power profiles
  - Optical quality
  - Scattering
- Material properties
  - Water content
  - Modulus
  - Wettability
  - Surface friction
  - Oxygen permeability
  - Refractive index
  - Spectral transmission
- Lens geometry
  - Diameter
  - Sagittal depth
  - Thickness
  - Radius of curvature
  - Edge shape.

Whereas measurement of some of these parameters requires specialist instrumentation and expertise, other parameters can be measured quite easily by clinicians for ‘on the spot’ trouble shooting in their contact lens practice.

Lens Conditioning According to ISO 18369-3

Because of the hydrophilic nature of all soft lens materials and their sensitivity towards environmental changes, proper conditioning of these lenses prior to any measurements is of critical importance. ISO 18369-3 prescribes that a standard phosphate buffered saline (PBS) with a pH of 7.4 ± 0.1 and an osmolarity of 310 ± 5 mOsm / kg is to be used to soak all lenses for at least 30 minutes. Generally, measurements are to be taken at a temperature of 20 ± 0.5 °C. Standard PBS is prescribed as it closely mimics the osmolarity and pH environment of tears on eye. In clinical practice, sterile 0.9% saline solution is more readily available and can also be used.

Optical Parameters

The optical parameters are most important for the visual performance of a contact lens on eye.

The visual performance of a contact lens is largely determined by the fidelity of optical parameters and prescription.

Light scattering and optical distortions are generally low and of less significance.

POWER AND POWER PROFILES

The three categories of soft lenses – spherical, toric and multifocal – require differing approaches to determine their relevant parameters. For single-vision spherical lenses, a single power reading for the sphere power is sufficient to evaluate the optical power. Toric lenses are rotationally non-symmetric and require the power measurement along at least two different meridians. Multifocal lenses are rotationally symmetric and the most interesting information is contained in the power profile along the diameter. The power profile determines the distance and add power, and the blending between these two powers.

For the contact lens practitioner, the simplest method to confirm the power of a particular contact lens is to place the lens on eye and perform an overrefraction (Plainis and Charman, 1998) to achieve best distance visual acuity. Although this technique is a viable method for prescribing contact lenses, its subjective nature and uncontrolled factors like pupil size and orientation / centration make this methodology unsuitable for precise and objective power measurements.

The focimeter is a simple optical instrument that is still widely used by manufacturers and practitioners to measure back vertex power (BVP) over a 4.5 mm central aperture in air (Fig. 7.1). A cross-shaped mire is projected through the lens and the image is brought into focus by turning the power drum. The BVP is then read off a dial connected to the power drum. Toric lens power can also be measured by first aligning the orientation marks on the lens and then rotating the mire to align with the flat and steep meridian of the toric optic zone. Focusing the line along the flat meridian will provide the sphere power. The cylinder power is the difference to the focus position of the steep meridian. The axis value is the angle between the flat meridian and the horizontal line. Most of the autolensometers work on a similar principle, but the power and axis measurements are taken automatically and the results displayed digitally (Fig. 7.2).

Careful handling and preparation is required when measuring lens power in air. It is recommended to clean the contact lens and then dab dry both surfaces before centring it on the lens support. Excessive drying or exposing the lens for too long (longer than around 10 seconds) will dehydrate the lens and change the optical power. In a ring test involving five laboratories, Hough et al. (1996) showed that standard deviations of 0.1–0.3 D for sphere and cylinder power can be achieved for ten repeated measurements of low-powered toric lenses using a manual focimeter.

The current state-of-the-art power-measuring instruments immerse the lens in a saline-filled cuvette to avoid dehydration effects. These instruments can also map the power of the complete optical zone from which all the optical power parameters can be extracted. Power-mapping instruments based on the Moiré deflectometry, Hartmann–Shack (HS) and the phase-shifting Schlieren principles are on the market.

The Moiré deflectometry instrument from Rotlex was the first commercially available power mapper and the first to be included in ISO 18369-3. It utilizes two precision gratings placed in the optical path of a collimated light beam that also passes through the contact lens inside the cuvette (Fig. 7.3). The fringe pattern generated by the gratings is captured by a camera and analysed. The local tilt angle of the fringes correlates to the local power of the lens. Thereby, an entire power map of the optic zone can be calculated and averaged values for sphere, cylinder and axis obtained.

Several instrument manufacturers have over the last 15 years utilized the Hartmann–Shack method to generate power maps of soft contact lenses. HS sensors consist of an array of microlenses and a two-dimensional photo detector array – generally a charge-coupled device (CCD) or complementary

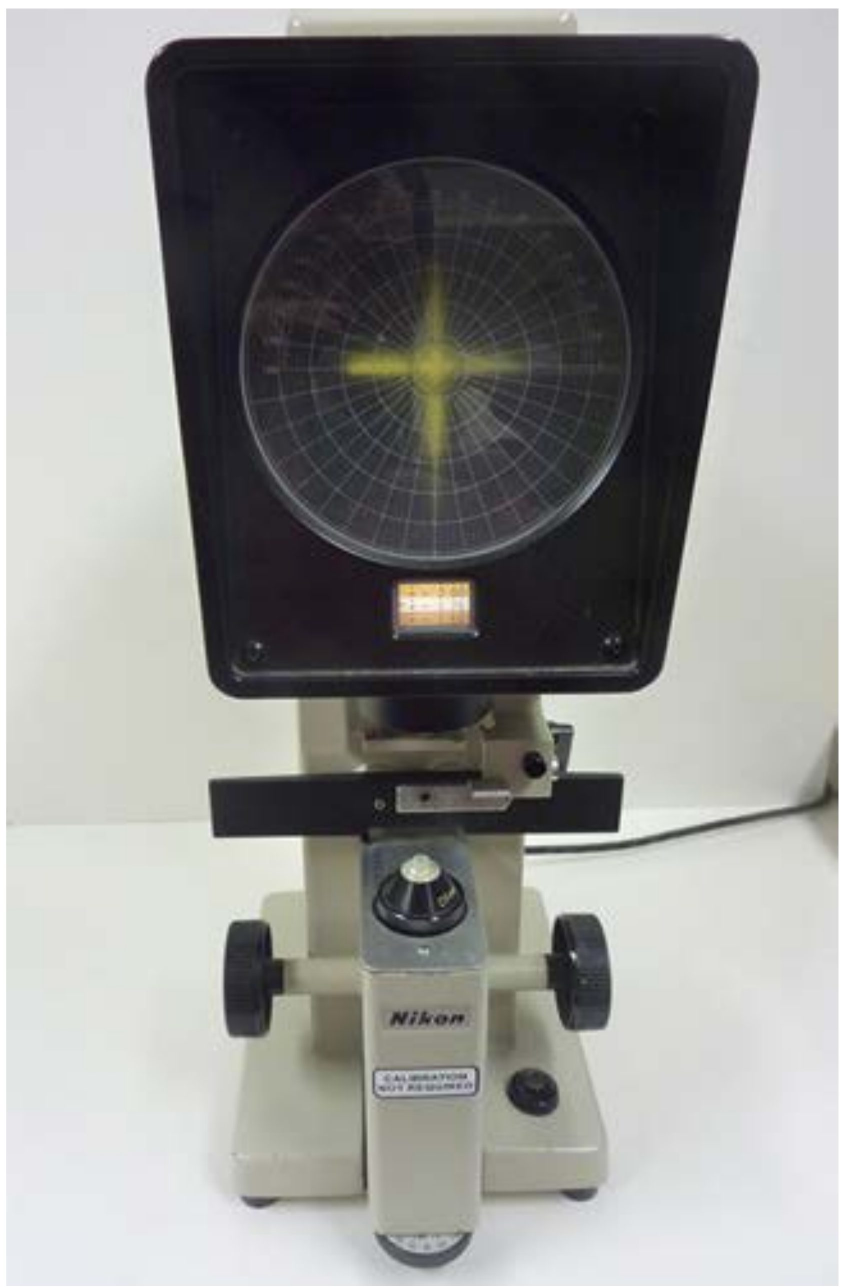

Fig. 7.1 Optical focimeter with 3 mm aperture adaptor. (Courtesy of Nikon.)

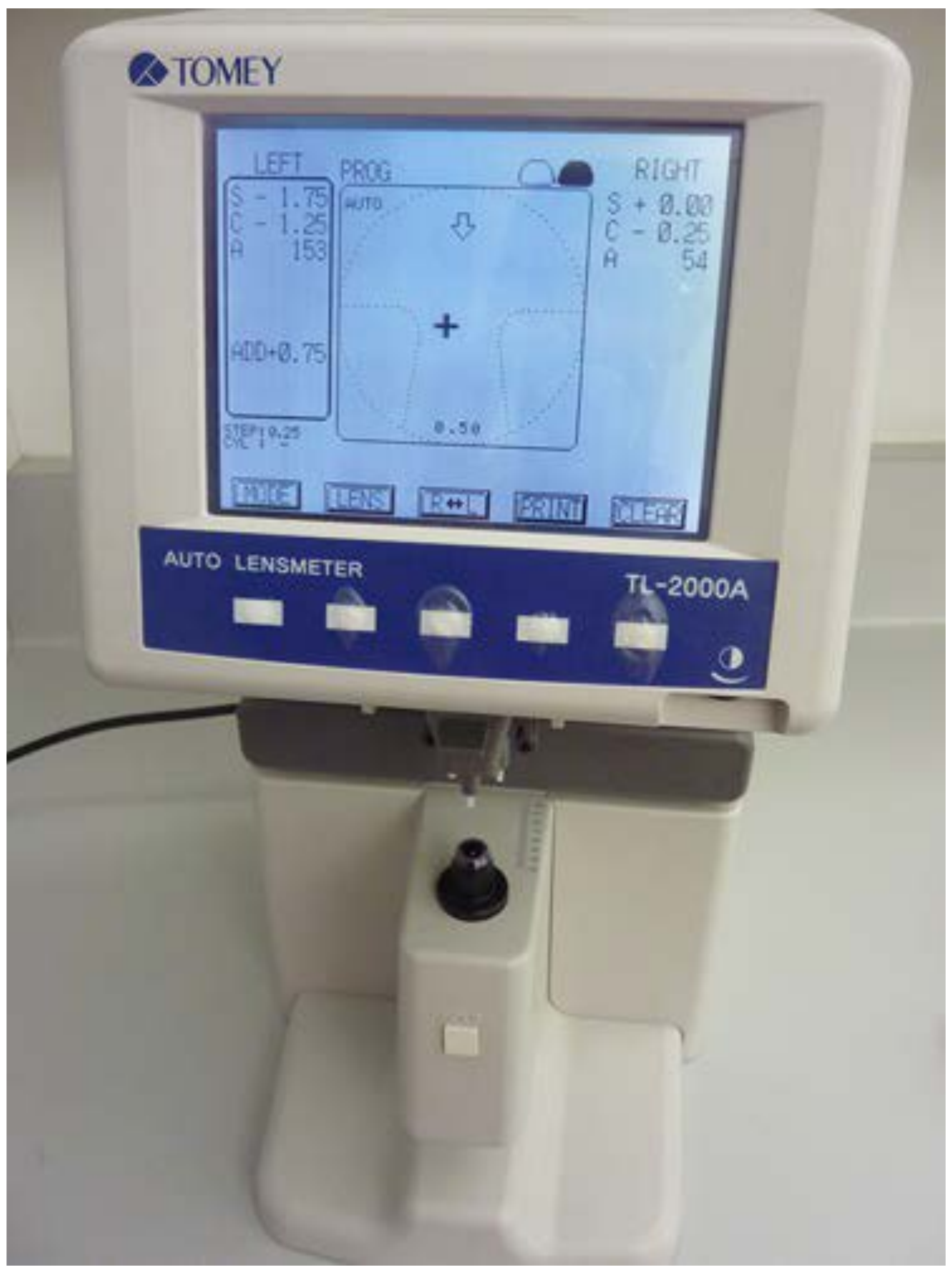

Fig. 7.2 Auto lensmeter with soft lens support. (Courtesy of Tomey.)

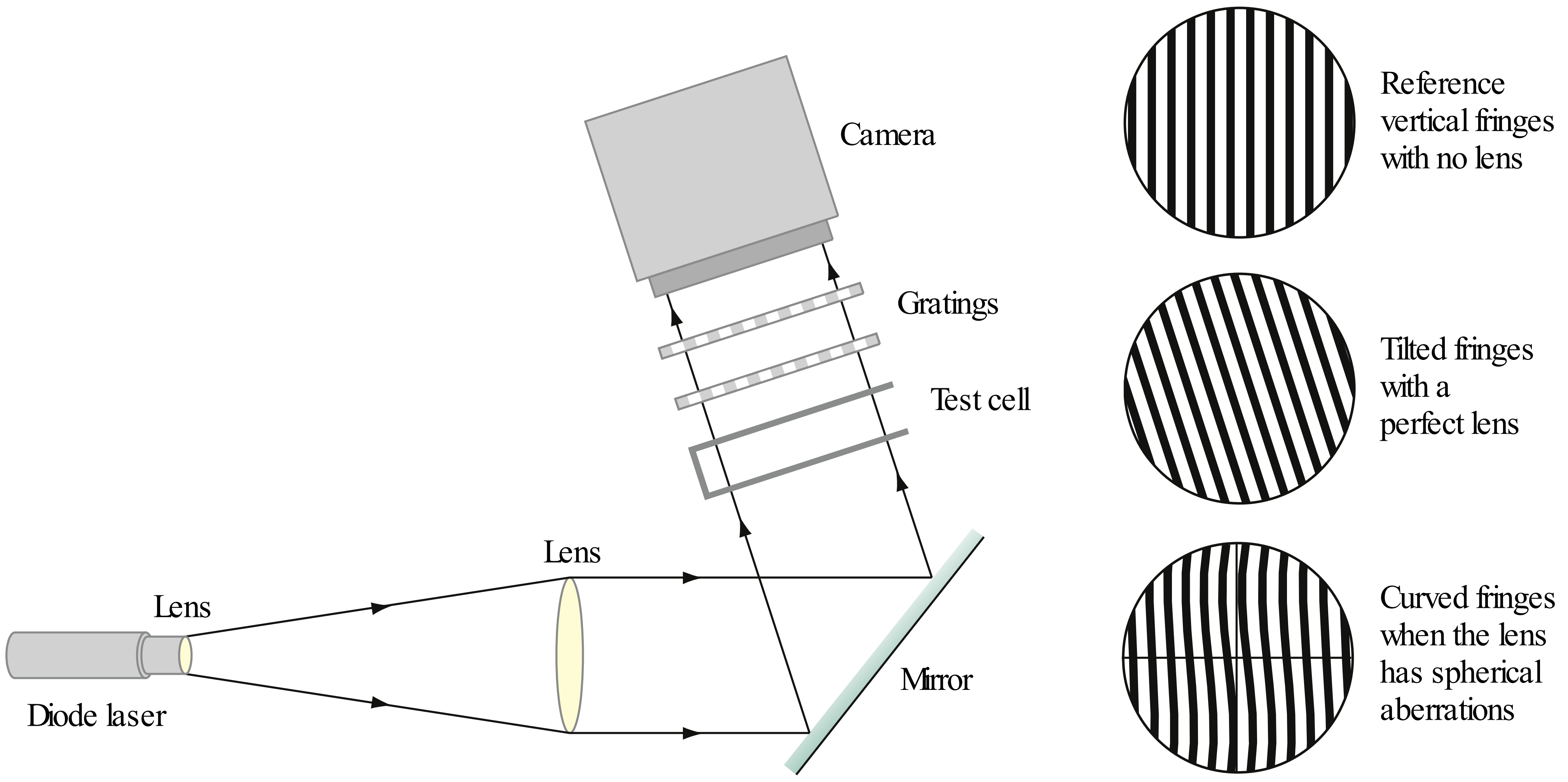
Camera
Gratings
Test cell
Lens
Lens
Diode laser
Mirror
Reference vertical fringes with no lens
Tilted fringes with a perfect lens
Curved fringes when the lens has spherical aberrations

Fig. 7.3 Principle of Moiré deflectometry.

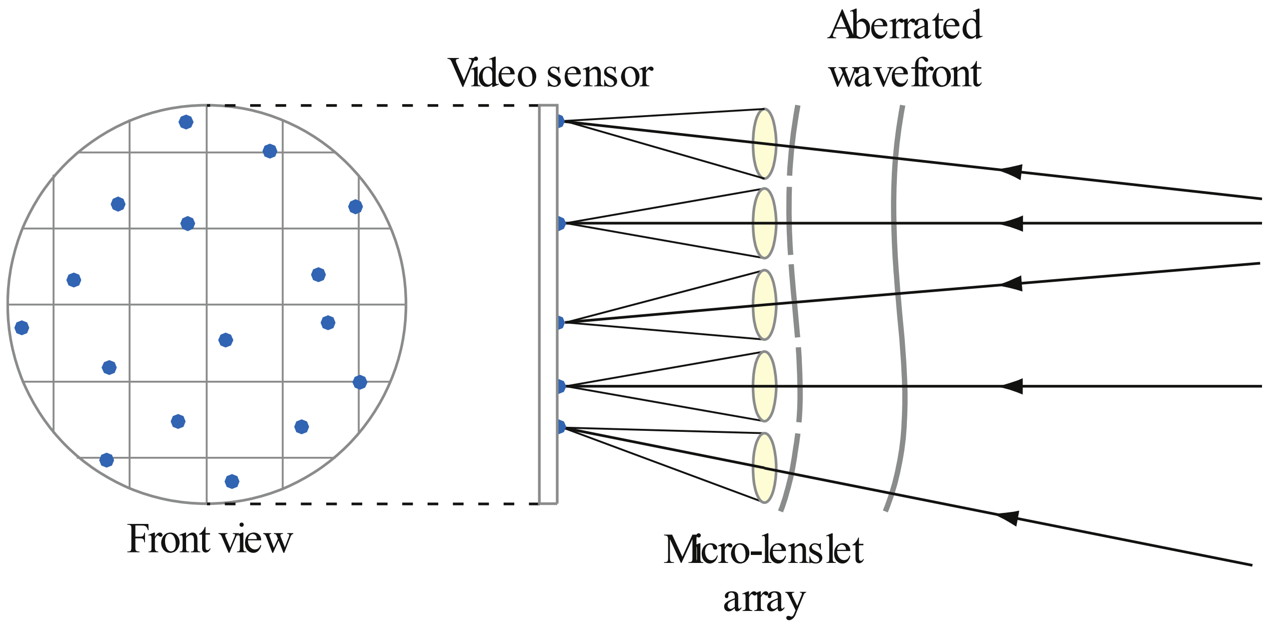

Fig. 7.4 Hartmann–Shack wavefront sensor.

Fig. 7.5 Power-mapping instrument based on Hartmann–Shack sensor. (Courtesy of Optocraft.)

metal-oxide semiconductor (CMOS) camera to measure the distortions within a wavefront (Jeong et al., 2005). The number of microlenses determines the achievable lateral resolution. The sensitivity and measurement range are determined by the focal length of the microlenses (Fig. 7.4). The instrument shown in Fig. 7.5 features a 101 × 101 micro-lenslet array providing a measurement range of ±20 D and a precision of 0.05 D. The instrument performs well within the ISO specified precision tolerances (Wagner et al., 2015). However, when power profiles are extracted, the reliability drops significantly towards the optical centre of the lens.

Phase-shifting Schlieren is the most recent technology to be implemented in a commercial instrument for the power mapping of contact lenses. The Nimo TR1504 from Lambda-X claims a measurement range of ±30 D and a repeatability of <±0.05 D. Repeatability is generally good, except for the central area close to the optical axis within which the confidence interval increases to over 0.8 D for some lens types. The Schlieren principle is explained in detail by Joannes et al. (2003); it is based on the knife-edge method, in which the single knife edge is replaced by a multiline filter element with sinusoidal transmission. The wavefront passing through the contact lens, the Schlieren lens, and the Schlieren filter is focused on a CCD camera to capture the Schlieren fringes (Figs. 7.6 and 7.7). By moving the filter laterally in small steps, a set of phase-shifted images is acquired from which the wavefront can be reconstructed.

The three methods and instruments used to generate power maps of soft contact lenses have a number of common features, as summarized below.

By measuring and mapping the complete optical zone, local power defects or deviations can be detected. Most instruments have implemented algorithms to generate a single quality number to quantify optical quality and use this as an additional pass/fail criteria.

Besides reporting the lower-order aberrations of sphere and cylinder power and axis angle, higher-order aberrations such as coma and spherical aberrations can also be obtained from the power maps. These are generally reported in the format of Zernike coefficients. Higher-order spherical aberrations can

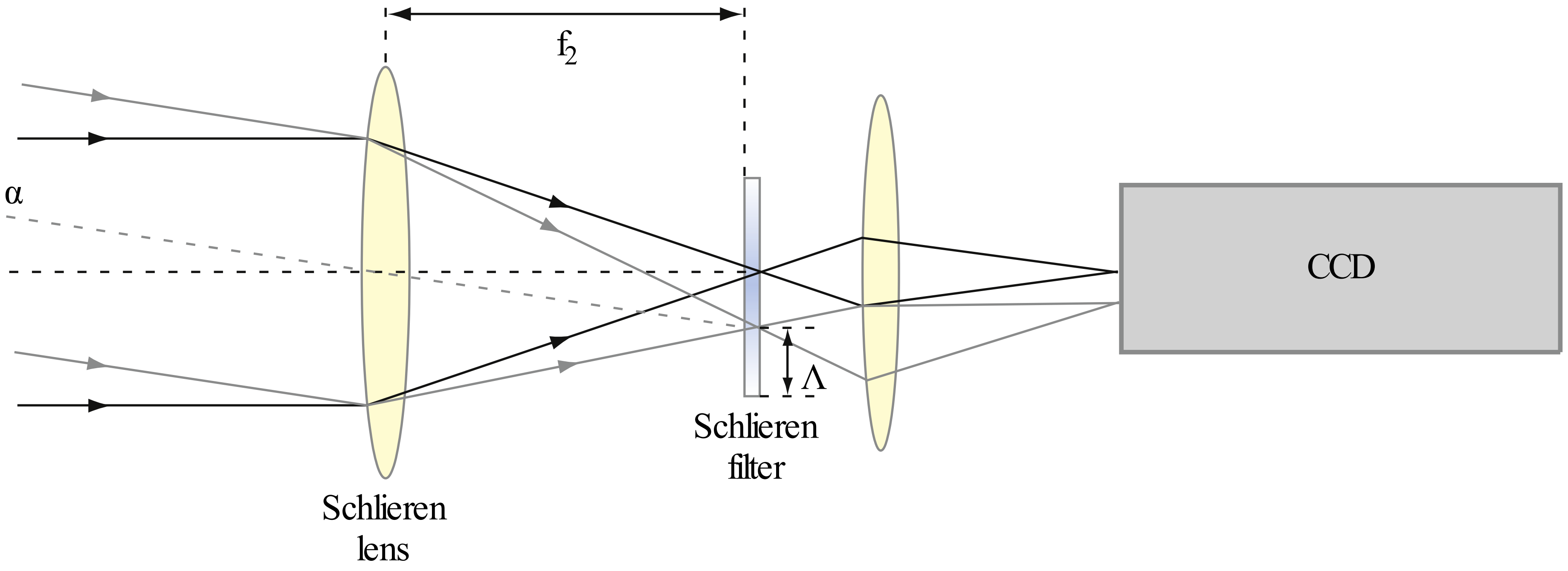

Fig. 7.6 Schlieren principle to measure wavefront aberrations.

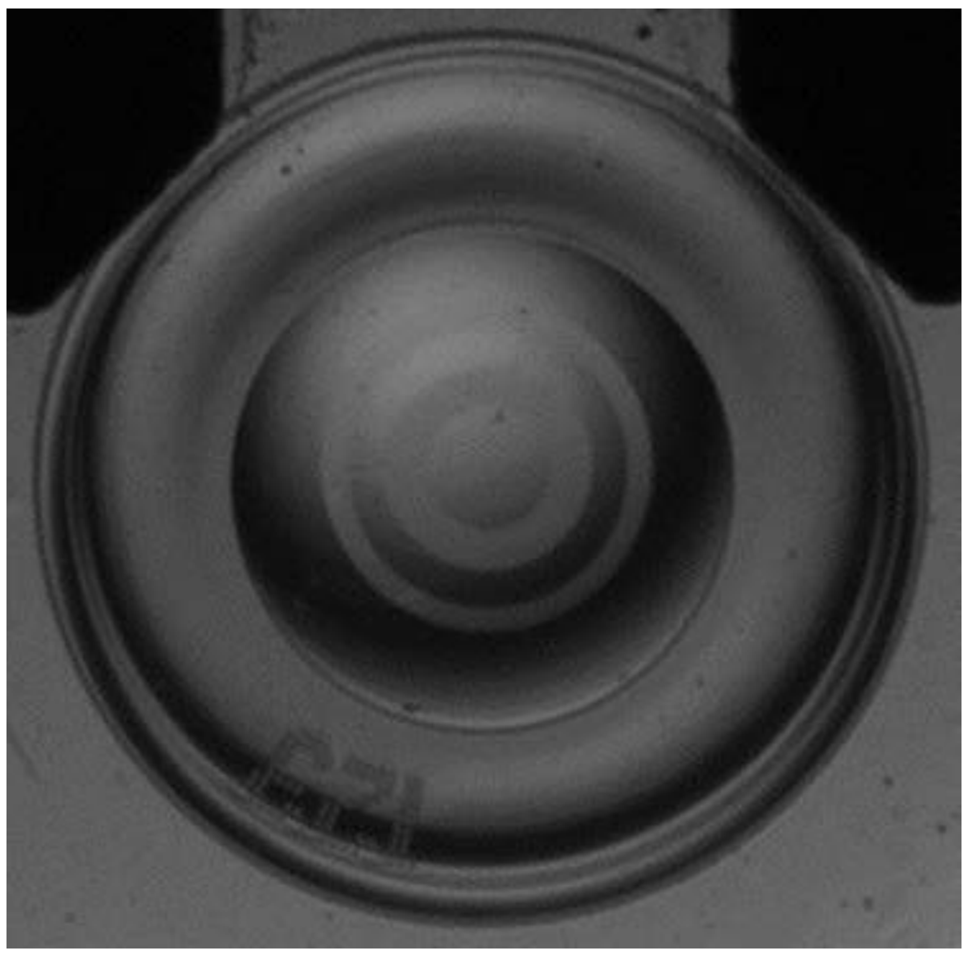

Fig. 7.7 Schlieren image of a multifocal lens.

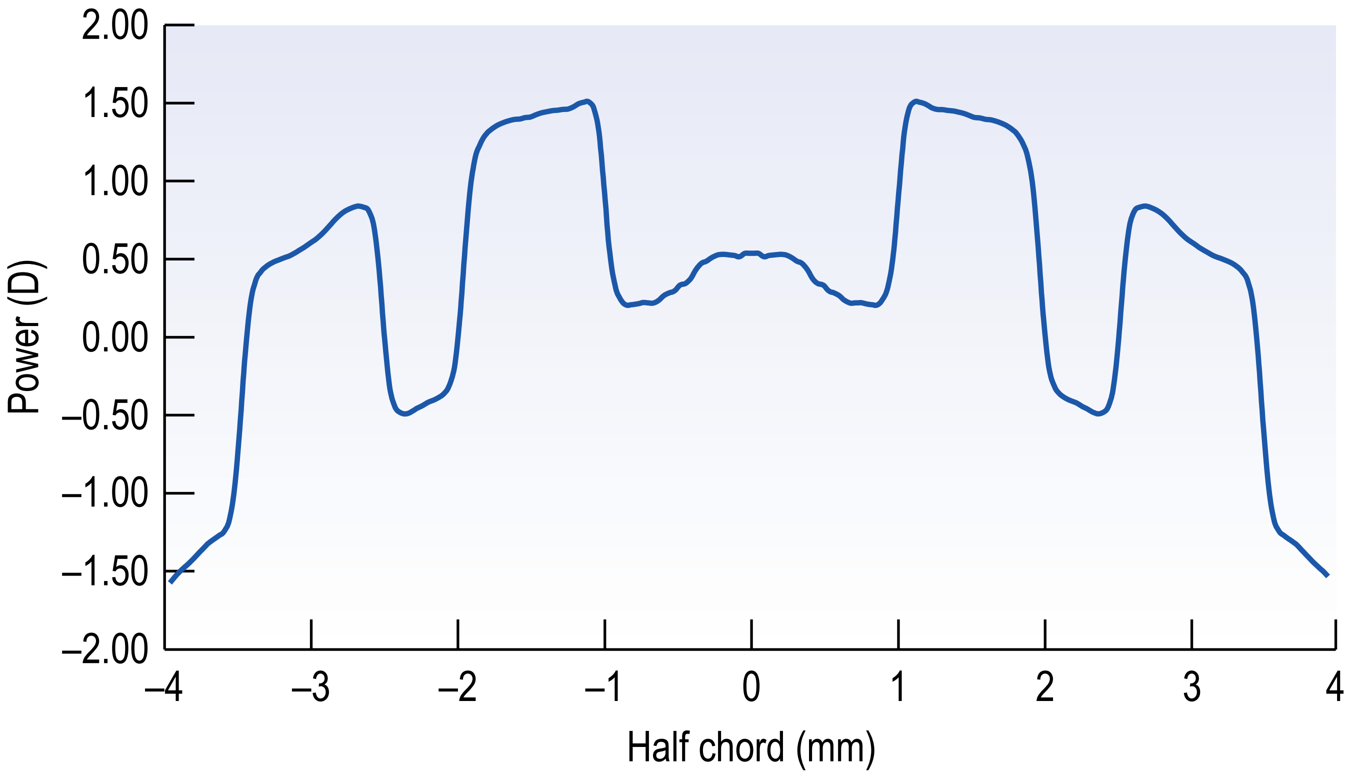

Fig. 7.8 Power profile of a bifocal contact lens with concentric distance and add rings.

also be plotted as power profiles, providing useful information, in particular for bifocal and multifocal lenses, as shown in Fig. 7.8.

Measuring the soft lens immersed in saline has the advantage of avoiding dehydration, but it also has some disadvantages that can significantly affect the measurement accuracy. The measured 'in saline' power needs to be converted back to 'in air' power using Eq. 7.1:

$$P_{air} = P_{saline} \times \frac{n_{lens} - n_{air}}{n_{lens} - n_{saline}} \qquad \text{Eq. 7.1}$$

where P_{air}: lens power in air, P_{saline}: lens power in saline, n_{air}: refractive index of air = 1, n_{saline}: refractive index of PBS = 1.3345, and n_{lens}: refractive index of lens material □1.39–1.42.

With most lens material having a refractive index of around 1.39–1.42 and the refractive index of saline being 1.3345, measurements in saline need to be about five times more accurate compared with a corresponding power measurement in air. The closeness of the refractive indices of saline and lens material also requires that both need to be known or measured with great accuracy. For example, an error of only 0.0005 for a 1.4100 lens material will lead to a false power reading of 0.35 D for a −6.00 D contact lens. Relying on the ISO 18369-2 tolerance of 0.005 for the refractive index of soft lens materials is therefore not sufficient when measuring optical power in a cuvette.

The back vertex power of a contact lens is referenced to the apex of the back surface. As this axial position is not known precisely for a lens placed inside the cuvette, instrument manufacturers use various methods to approximate that location for their power calculations using thin or thick lens formulae. The best results can be achieved by entering values for centre thickness and base curve for each particular lens.

The method of power mapping has the disadvantage that, close to the optical centre of the lens, even very small errors in the detection of the incoming wavefront angle can lead to a very large error in the calculated power. To alleviate this problem, the data-processing algorithms in most instruments utilize noise filtering and extrapolation methods to smoothe the power values around the optical axis.

OPTICAL QUALITY

Factors that can compromise the optical quality of a soft contact lens are inhomogeneous material, surface scratches or deposits, lathe marks, material inclusions or air bubbles. The more obvious defects can be picked up with any of the power-mapping instruments or careful observations using a slit lamp. More subtle defects can only be detected using more sophisticated equipment like the knife-edge tester (Ho and Ehrmann, 2000) (Fig. 7.9) or thickness profilers (Maiden et al., 2010).

SCATTERING

Scattering is generally of little concern with soft contact lenses. It might be observed occasionally, caused either by surface deposits or contamination or by manufacturing defects affecting the

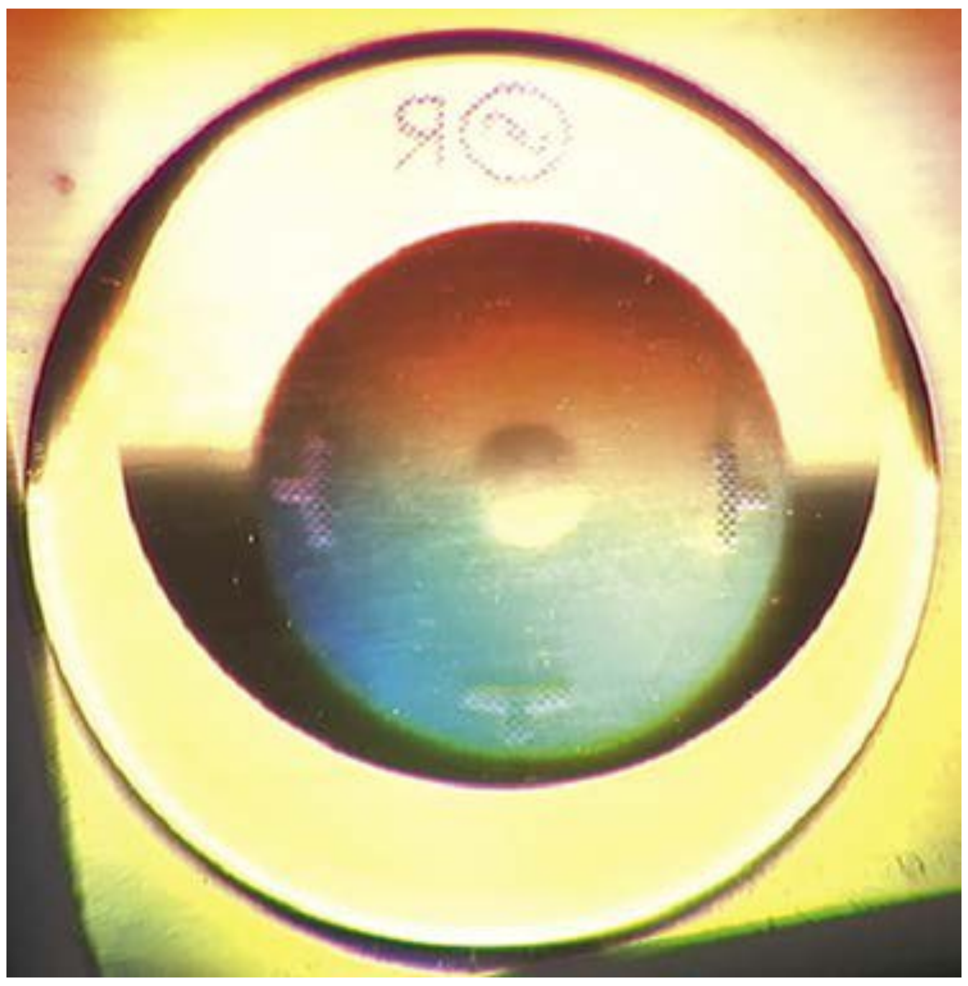

Fig. 7.9 Colour-coded power map of a prism ballast, soft toric lens captured using a knife-edge optical quality tester.

bulk of the material. Quantitative assessment is best done using a dark-field microscope. In vivo, optical coherence tomography instruments, such as the one used by Kałużny et al. (2006), can be employed to determine the degree of back scattering.

Material Properties

Properties can vary widely between different soft lens materials and concomitantly, on-eye performance in terms of comfort, vision, fit and ocular health. For traditional hydrogel materials, most of the properties, including modulus, oxygen permeability, refractive index and wettability are linked to the water content of the material. With the introduction of silicone hydrogels, coated lens surfaces and additives in packaging solutions, properties are less predictable and need to be measured individually for each material.

WATER CONTENT

As summarized by Gonzales-Meijome et al. (2006), there is an almost linear relationship between water content and refractive index for hydrogel materials. This relationship makes it possible to derive the water content of a material by measuring its refractive index. Refractometers such as the CL-1 Soft Contact Lens Refractometer from Atago (Japan) have a scale that indicates the water content converted from the refractive index reading. The accuracy that can be expected from this method is in the order of ±5% (Nichols et al., 2003).

The gravimetric method is applicable to all soft lens materials and is generally more accurate, however, this method is destructive and requires specialized laboratory equipment. It is based on the ISO 18369-3 (International Organization for Standardization [ISO], 2006c) definition of water content as:

$$\omega_{H_2O} = \frac{m_{H_2O\ \text{hydrated material}}}{m_{\text{hydrated material}}} \times 100$$

where $m_{H_2O\ \text{hydrated material}}$ = mass of water in the hydrated material, and $m_{\text{hydrated material}}$ = mass of the hydrated material.

In this context, dissolved solutes such as sodium chloride and buffers contribute to the mass of the hydrated material.

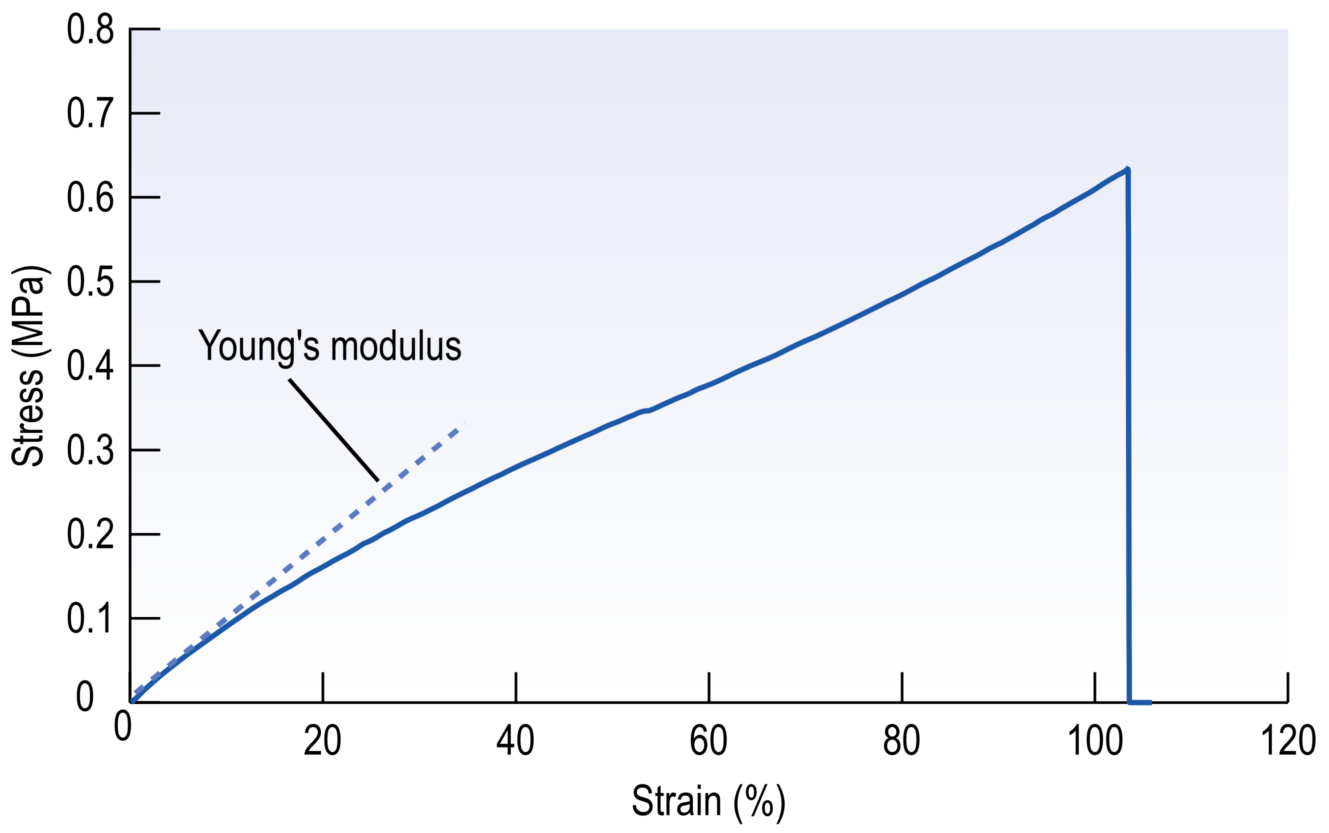

Fig. 7.10 Stress versus strain curve of a typical contact lens material sample.

From this overall value, water content is calculated after measurement of the dry mass and hydrated mass of a contact lens at room temperature:

$$\omega_{H_2O} = \frac{m_{\text{hydrated}} - m_{\text{dry}}}{m_{\text{hydrated}}} \times 100$$

where m_{hydrated} = mass of the hydrated material and m_{dry} = mass of the dry material.

The key to achieving good accuracy with this method is the consistent removal of excess surface water by dry blotting. Sample lenses are then dried in an oven and the weight measured again using an analytical balance.

MODULUS

Material stiffness is commonly measured and expressed as the modulus of elasticity, or Young's modulus. This modulus is defined as the slope of the stress/strain curve of a material under tensile or compression deformation. 'Strain' is the elongation or shortening of the test sample expressed as a percentage. 'Stress' is the experienced force divided by the cross-sectional area of the sample. In order to make reliable measurements, it is preferable to have a consistent cross-section of the sample over the full length of the sample. Contact lenses are too thin to make any meaningful modulus measurements in compression mode. For the tensile measurements, a 3–6 mm wide strip from the centre of a −1.00 D contact lens is cut and its harmonic mean thickness and width measured within the central 8 mm of its length to obtain the average cross-sectional area. The sample is then loaded into the tensile testing instrument and clamped on either end so that the free length between the clamps is no more than the optic zone diameter of the lens. From its initial free length, the sample is elongated by 10–15% and the corresponding force/elongation curve recorded (see Fig. 7.10). The force scale is converted to stress by dividing through the cross-sectional area. Most commonly, the relatively linear section between 4% and 8% elongation is used to fit a straight line, the slope of which is the Young's modulus.

Using the same instrumentation and sample preparation, it is possible to also measure the ultimate tensile strength (UTS), the material toughness, and stress relaxation. The ultimate tensile strength is the stress inside the material at the point at which the sample breaks:

$$\text{UTS} = \frac{\text{force at breakpoint}}{\text{original cross-sectional area}}$$

Material toughness is the area under the stress/strain curve up to the breakpoint (Fig. 7.10). Stress relaxation determines the dynamic behaviour of a material under stress.

Most plastic materials show some form of relaxation over time in response to applying an initial stress. To measure the time constant and amplitude of this behaviour, the contact lens sample is quickly elongated to a predetermined percentage of its free length and then held for several minutes while recording the change in the force required to hold the sample. The corresponding stress over time curve is plotted and, by fitting an exponential function, the time constant and amplitude are extracted (Fig. 7.11). 'Creep' is the inverse of stress relaxation whereby a constant load is instantly applied to the sample and the subsequent continuing elongation is recorded.

Several factors need to be considered in terms of instrumentation and methods when measuring the mechanical properties of soft contact lens materials. Mechanical properties of plastic materials are temperature sensitive and the sample temperature needs to be maintained and recorded at either room temperature (20°C) or on-eye temperature (34°C). Full hydration of the contact lens samples needs to be maintained throughout the measurement procedure. Ideally, all measurements should be performed with the samples fully immersed in saline to avoid changes in dimension and stiffness. However, there are very few commercial instruments that can provide this option.

Tranoudis and Efron (2004) demonstrated that modulus measurements can be made in air when the samples are fully hydrated beforehand and then monitored to ensure the water film on the surface remains intact. The actual forces required to stretch the contact lens samples are rather small (<500 mN) and most tensile-testing equipment lacks sufficient sensitivity to resolve the small changes. The Vitrodyne 2000 was a suitable commercial instrument, but is no longer available (Fig. 7.12). Some research groups have developed or modified instruments to make them suitable for soft contact lens materials (Ehrmann et al., 2008; Young et al., 2010).

A different approach to measure mechanical properties is through the method of microindentation. This method has several advantages including being non-destructive, requiring only a small sample size, and being easily implemented on immersed samples, but it is an indirect method to obtain modulus values and therefore relies on assumptions and conversion factors. The indentation probes can be as small as the ones used in atomic force microscopy (Selby et al., 2014) or larger spheres as used by Chen et al. (2007), which can make it difficult to separate surface properties from those of the bulk material.

WETTABILITY

Surface wettability is an important factor affecting biocompatibility and on-eye comfort. For conventional hydrogel materials surface wettability is closely correlated with the water content of the material. However, the hydrophobic nature of silicone made it necessary to surface coat the first generation of silicone hydrogel contact lenses to make them compatible with the ocular environment. Meanwhile, additional treatments have been applied to enhance insertion or all-day wettability by adding wetting agents to the material or packaging solution (Fonn, 2007). The easiest way for practitioners to assess and compare surface wettability is on eye, using a tear-scope (Guillon, 1998), and measuring the tear break-up time. This tear-scope method is suitable only as a relative measure because tear quality can vary considerably between patients. Similar observations of the pre-lens tear film can also be made using a slit lamp or keratometer. A tear break-up time of less than 4–8 seconds is likely to adversely affect comfort and vision (Guillon, 1998).

For more objective wettability measurements of lens surfaces, various in vitro methods have been developed and used in research laboratories. The contact angle formed between the surface and the liquid touching the surface is a good indicator of surface wettability. The angle can be measured either by the deflection of a laser beam (Bush et al., 1988) or by capturing an image and analysing the cross-sectional profile (Ketelson et al., 2005) (Fig. 7.13). The standard method (sessile drop) is to place a drop of saline on the convex side of the contact lens.

To avoid lens dehydration, the inverse method (captive bubble), whereby the lens is immersed in saline and an air bubble is placed on the lens surface, has also been implemented and demonstrated to provide reliable results (Maldonado-Codina and Morgan, 2007). As an alternative to the contact angle method, the meniscus height or curvature can also be measured to quantify surface wettability either in vivo (Doughty et al., 2001; Nichols and Sinnott, 2006) or ex vivo. The lens is immersed in saline, held vertically and slowly pulled out until only the lower half remains immersed. A cross-sectional image is taken of the

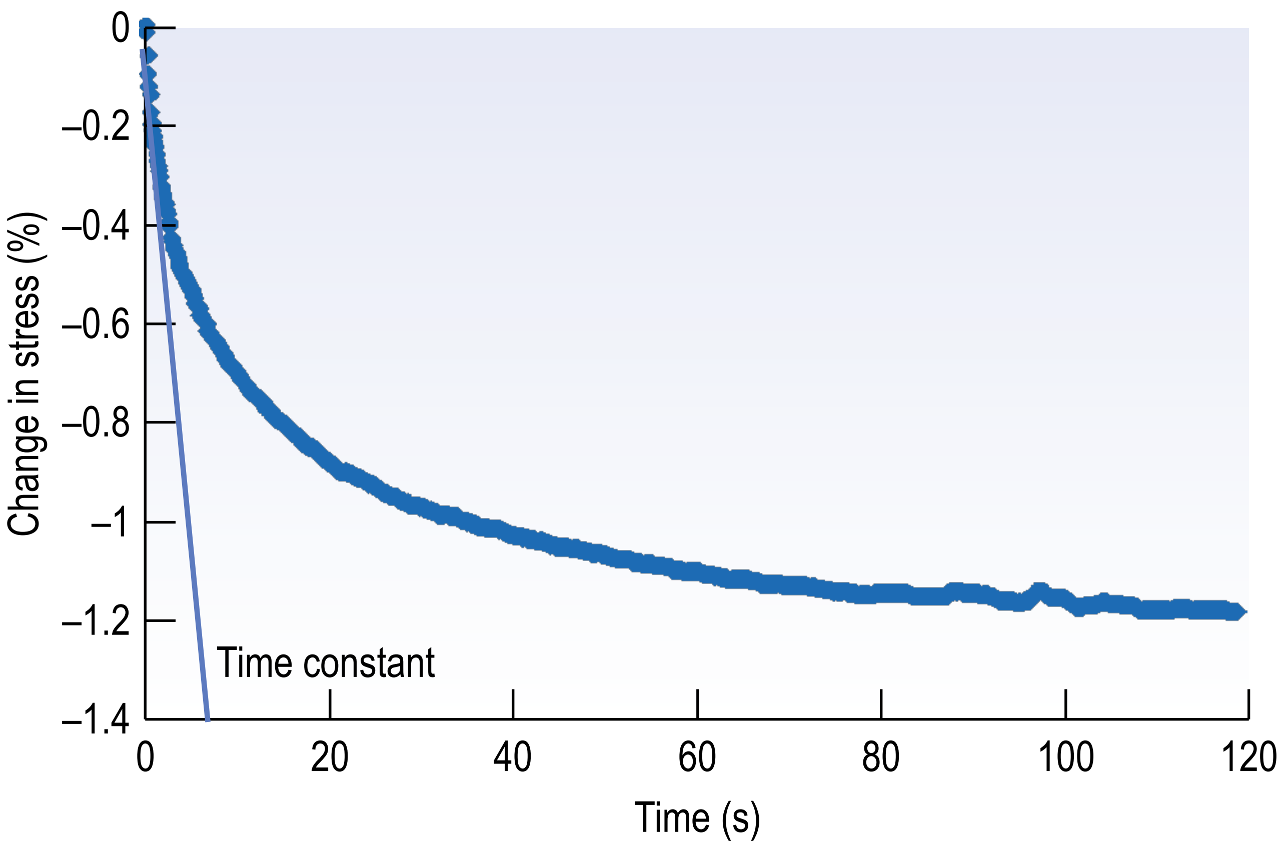

Fig. 7.11 Stress relaxation curve showing a decrease in stress over time in response to 8% elongation.

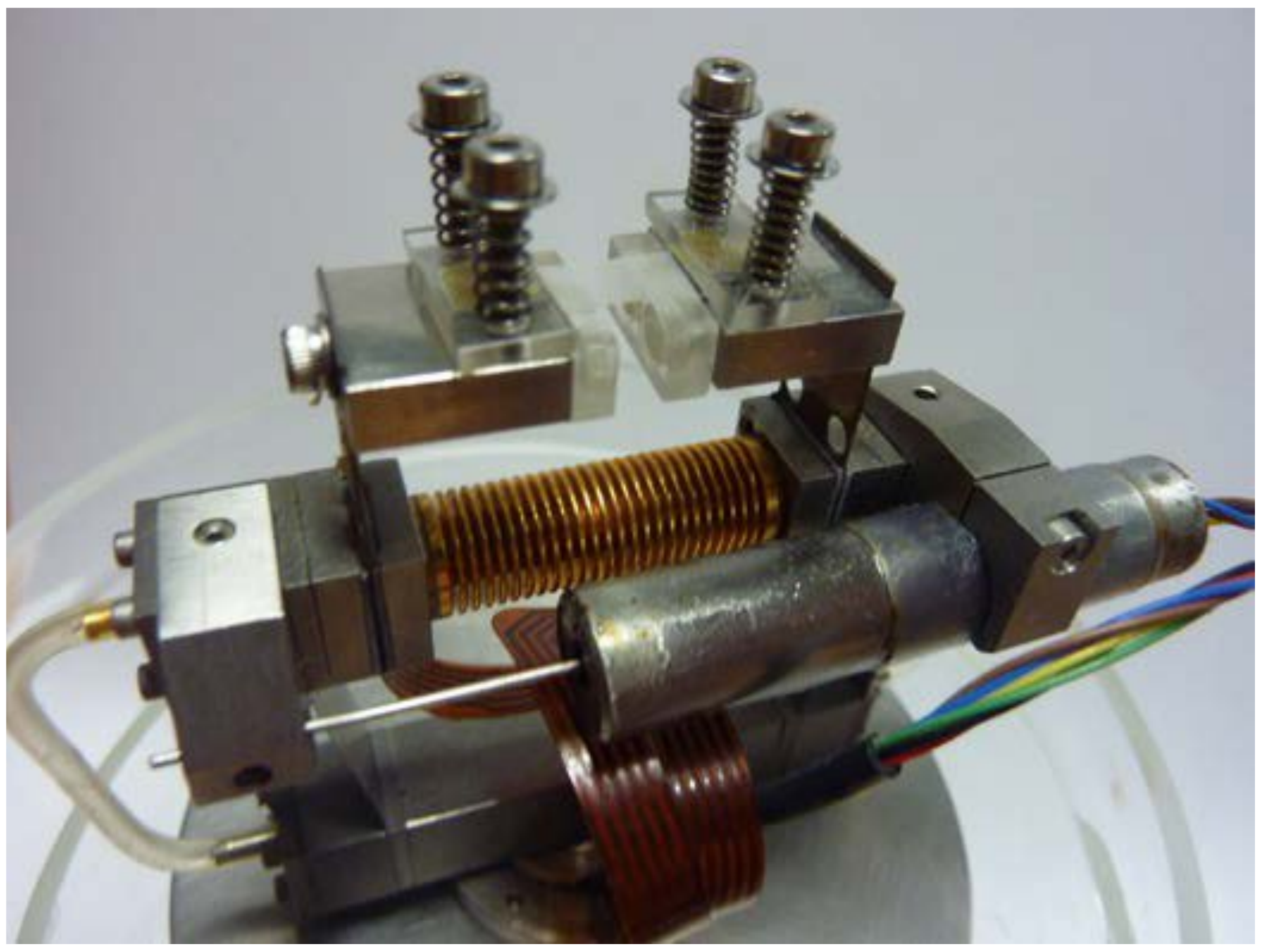

Fig. 7.12 Vitrodyne 2000 material tester.

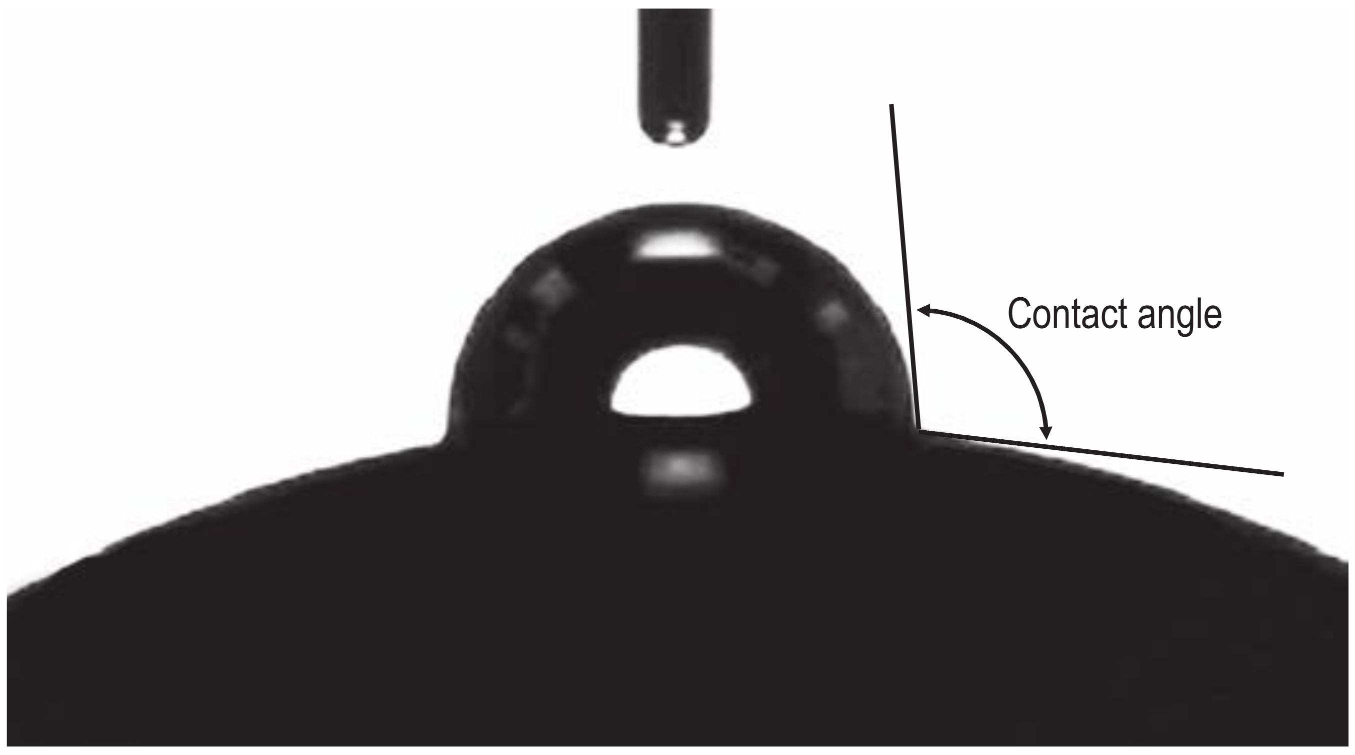

Fig. 7.13 Sessile drop method to measure contact angle as an indicator of surface wettability.

liquid and lens surface and the meniscus formed in between. By image analysis or ruler, the meniscus height or radius can be determined. The Wilhelmy plate technique is similar procedurally, but, rather than measuring the meniscus height, the vertical force exerted by the meniscus is determined (Tonge et al., 2001).

With all four of these methods, measurements can be made under receding or advancing conditions. Under the receding condition, the lens surface is wet at the point of measurement, whereas, with the advancing condition, the liquid advances over an area that has been exposed to air.

SURFACE FRICTION

Surface friction has been implicated in influencing on-eye comfort but there is no firm evidence to support this hypothesis (Ngai et al., 2005). This lack of evidence might partly be due to the difficulties in measuring on-eye friction between the lens and the cornea and lid. Published in vitro friction measurements against various references can vary by orders of magnitude between lens types as well as between particular studies and methods (Jones et al., 2013).

The friction coefficient is the ratio between the force normal to the surface and the force parallel to the surface when two surfaces slide against each other. As there are always two surfaces involved the choice of reference surface can have a significant effect on the friction results. For contact lenses, glass has been used most commonly, but metal, plastic, epithelial cells and even bovine conjunctival tissue have been used (Rennie et al., 2005; Dunn et al., 2008; Roba et al., 2011; Zhou et al., 2011; Samsom et al., 2012). Besides the reference surface, the type of lubricant also needs to be taken into consideration. Saline or artificial tear fluid are most suitable to maintain hydration and to simulate on-eye conditions. Other fluids can also be used, for example to specifically study effects of enriched packaging solutions or eye drops with wetting agents.

Of the two types of friction, static and kinetic, only the kinetic one is of interest for on-eye performance. A soft lens is constantly moving on the eye, a bound lens provides no more tear exchange and should be removed.

The simplest way to measure friction is by using the ‘friction angle’ method. The material sample is placed on a flat – usually glass – plate and the plate is tilted slowly. The tilt angle at which the sample starts moving is the friction angle, the tangent of which is the static friction coefficient. The kinetic coefficient can be determined by starting with a steeper angle, and repeatedly pushing the sample upwards while lowering the angle. The angle at which the sample stops sliding downwards corresponds to the kinetic friction coefficient. A lens holder and a small weight may be required to mount and provide support for the contact lens. Instruments that measure the normal and tangential forces while the sample is moved along the reference surface have also been developed and measurement data presented (Dunn et al., 2008; Roba et al., 2011).

Ebatco (MN, USA) and CSM Instruments (Peseux, Switzerland) are two suppliers that offer instruments suitable for soft contact lens friction measurements. Modified rheometers have also been used to measure lens friction by rotating the sample against the reference surface (dos Santos et al., 2009). The use of AFM probes to determine surface friction has been reported (Kim et al., 2001); however, there is no clear evidence that the measurement results actually represent surface friction as it is generally understood, and that these measurements are unaffected by other surface properties.

The wide range of kinetic friction coefficients, from 0.02 to 0.6 (dos Santos et al., 2009; Roba et al., 2011) indicate that the methodology has a great effect on the results. Material comparisons should be made only within data from the same study.

OXYGEN PERMEABILITY – TRANSMISSIBILITY

Oxygen permeability is a material property that defines how easily oxygen passes through a particular material. The corresponding contact lens property is oxygen transmissibility, which is the permeability divided by the lens thickness. As the oxygen flow can be measured only through an actual contact lens, it is the oxygen transmissibility that is measured and then converted to permeability by multiplying it with the average measured lens thickness (t). The permeability coefficient (Dk) can be expressed as the product of diffusion (D) and solubility (k) and its common unit is Barrer. The transmissibility thereby becomes Dk/t (ISO, 2006d). ISO 18369-4 prescribes two different methods to be used for different types of lenses or permeability ranges. The polarographic method is applicable to all material types having an oxygen permeability from 0 to 145, while the coulometric method is applicable only to non-hydrogel materials. However, Morgan et al. (2001) have demonstrated that the coulometric method is also viable for soft lenses if certain conditions are met.

With the polarographic method, the contact lens is in direct contact with the oxygen-sensing probe, whereas with the coulometric method, the oxygen diffused through the contact lens is carried by nitrogen gas to the oxygen sensor (Fig. 7.14). In both methods, the central 4–7 mm zone is exposed to 21% O_2 saturated saline, which is stirred continuously to minimize boundary layer effects. Temperature of the apparatus, lens and saline is to be maintained at 35° C. Despite the stirring, boundary layer effects can still reduce the oxygen flux through the lens. To eliminate this measurement error, lenses of different thickness can be measured and the resulting offset subtracted (Morgan et al., 2001). ISO 18369-4 also recommends a correction for the ‘edge effect’, which is caused by oxygen flowing in sideways around the perimeter of the clamped area.

There is currently no commercial equipment available for either of these methods. The few manufacturers and laboratories that have oxygen permeability measurement capabilities either use instruments adapted from the packaging industry or have developed their own apparatus.

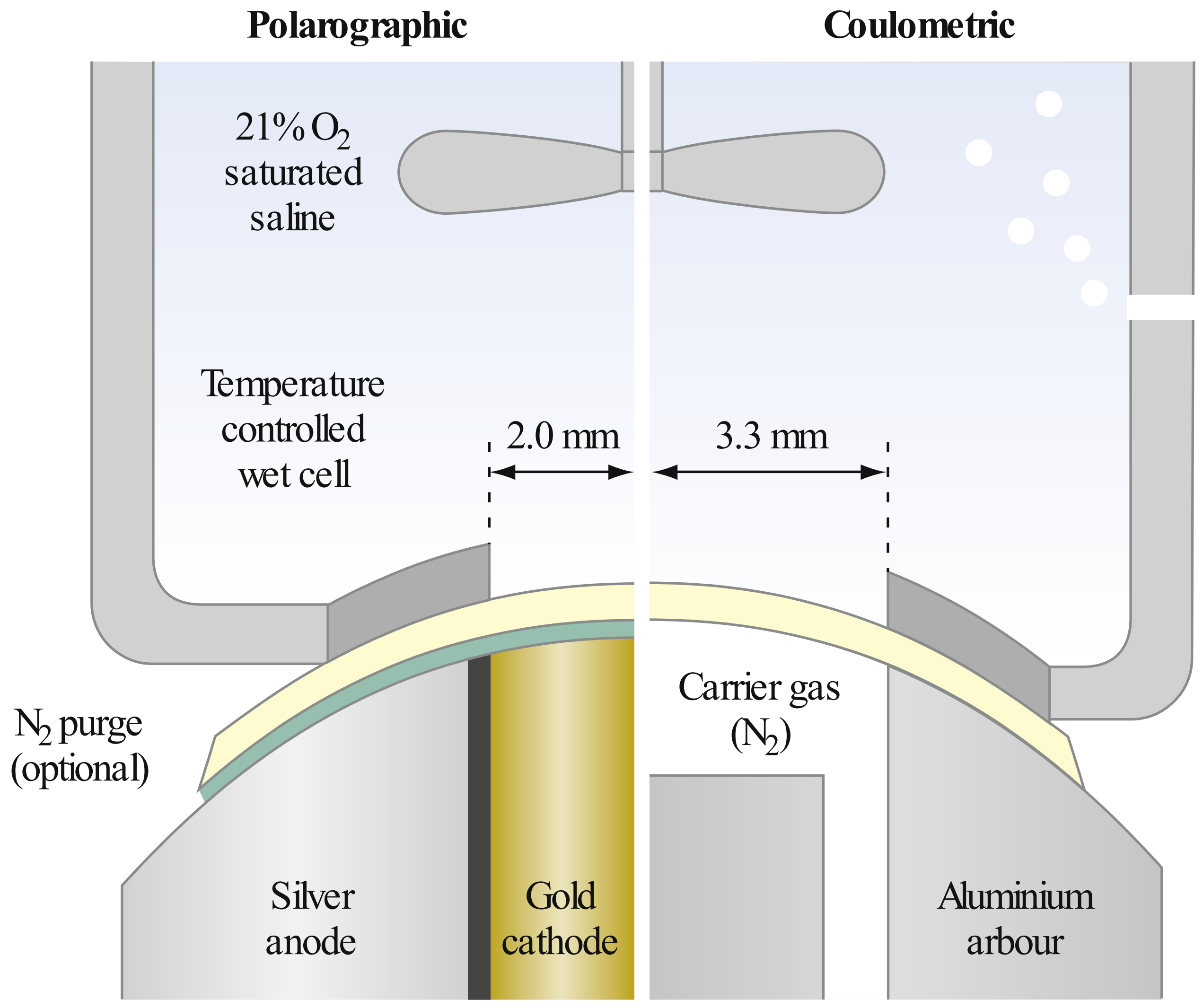

Fig. 7.14 Comparison between polarographic and coulometric oxygen transmissibility measurement methods. (From Morgan M. F., Brennan, N. A. & Alvord, L. (2001). Comparison of the coulometric and polarographic measurement of a high-Dk hydrogel. Optom. Vis. Sci., 78(1), 19–20. ©2001 American Academy of Optometry.)

To convert the measured oxygen transmissibility into permeability, transmissibility needs to be divided by the harmonic mean radial thickness of the measurement area.

Not only is oxygen transmissibility a critical material property when it comes to maintaining good ocular health but, as Cerretani et al. (2012) have demonstrated, sufficient ion permeability is also important, particularly with regard to avoiding lens binding to the cornea. The measurement methods for ion permeability are similar to those for oxygen, except that the sensing element responds to ions instead of oxygen (Guan et al., 2011).

REFRACTIVE INDEX – DISPERSION

Abbe refractometers are the preferred choice of instrument for measuring the refractive index of hydrogel contact lenses. They are easy to use and provide the required precision of 0.001. Abbe refractometers measure the critical angle of incidence for total internal reflection, which is directly correlated to the refractive index.

$$n = n' \times \sin\alpha \qquad \text{Eq. 7.2}$$

where n = refractive index of test sample, n′ = refractive index of reference surface, and α = critical angle of incidence upon reference surface.

For the contact lens practitioner, there are hand-held instruments on the market (Fig. 7.15), some of which have a scale that converts refractive index into percentage water content for hydrogel materials. Bench-top instruments such as the Abbe Mark III Refractometer (Reichert, NY, USA) and the Standard Abbe Refractometer from Edmund Optics (Barrington, NJ, USA) are generally more accurate. Consideration needs to be given to the illuminating wavelength as some materials can have noticeable dispersion. White light will give an average over the full visible spectrum. ISO 18369-4 specifies a single wavelength of 546.1 nm or 587.6 nm. The CLR12-70 (Index Instruments Ltd, Peterborough, UK) is one of the few dedicated instruments for contact lens materials (Fig. 7.16).

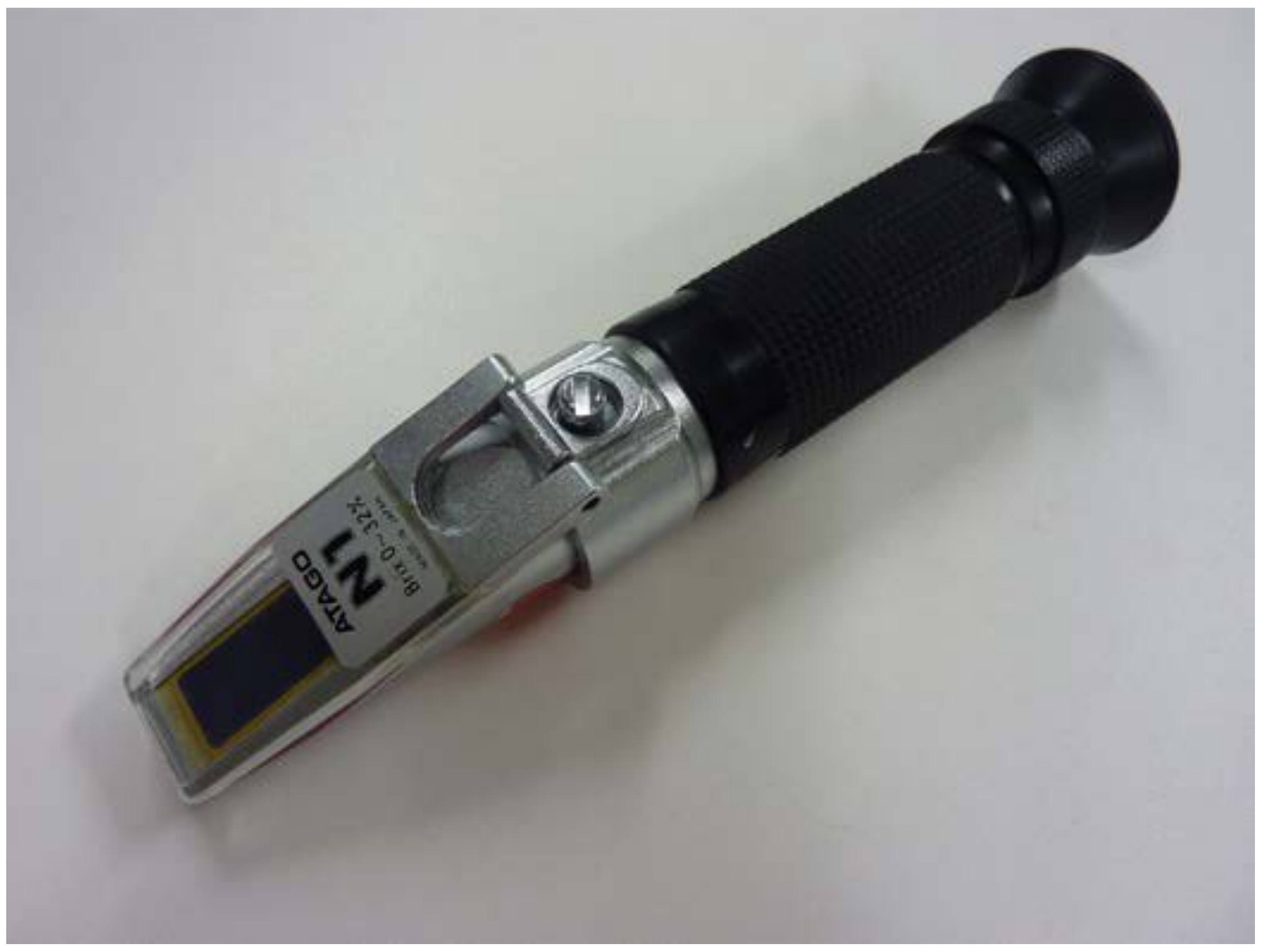

Fig. 7.15 Hand-held soft lens refractometer. (Courtesy of Atago.)

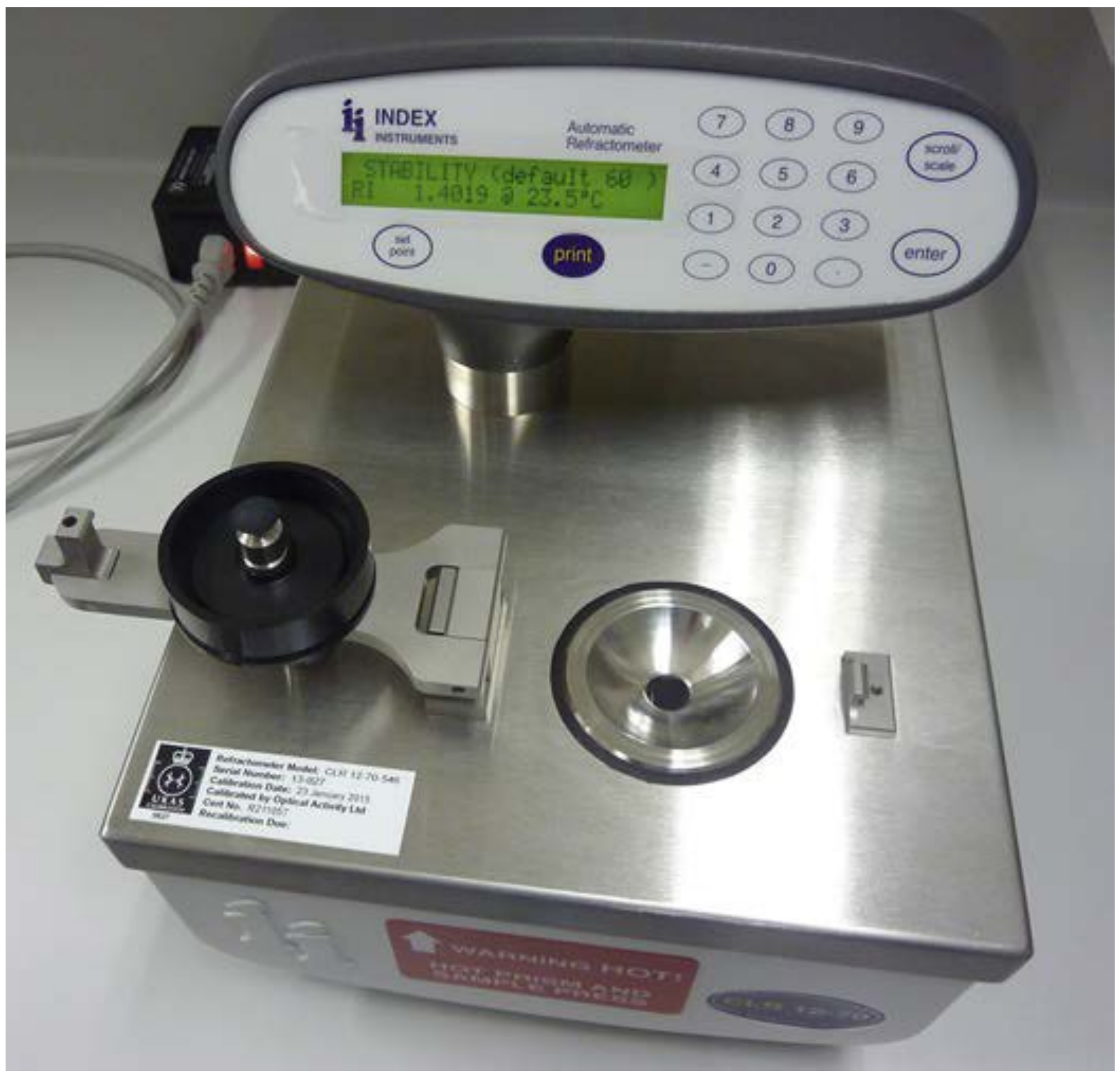

Fig. 7.16 CLR12-70 refractometer. (Courtesy of Index Instruments.)

SPECTRAL AND LUMINOUS TRANSMITTANCE

Spectral transmittance is defined as the ratio of transmitted spectral radiant flux to the incident spectral radiant flux. The luminous transmittance of the contact lens is obtained by measuring and integrating the spectral transmittance over the 280–780 nm wavelength spectrum in small increments (<10 nm) and weighing the radiant flux spectrally by the relative spectral luminous efficiency function of the eye (ISO, 2006c). Measurements and transmittance are specified in saline condition.

In order to make accurate measurements independent of the lens power, integrating spheres are used to determine the total transmitted luminous flux as prescribed in ISO 18369-3. Still, many research groups have used standard single- or dual-beam spectrophotometers and either ignored the lens power effect or taken measures to reduce its influence (Harris et al.,

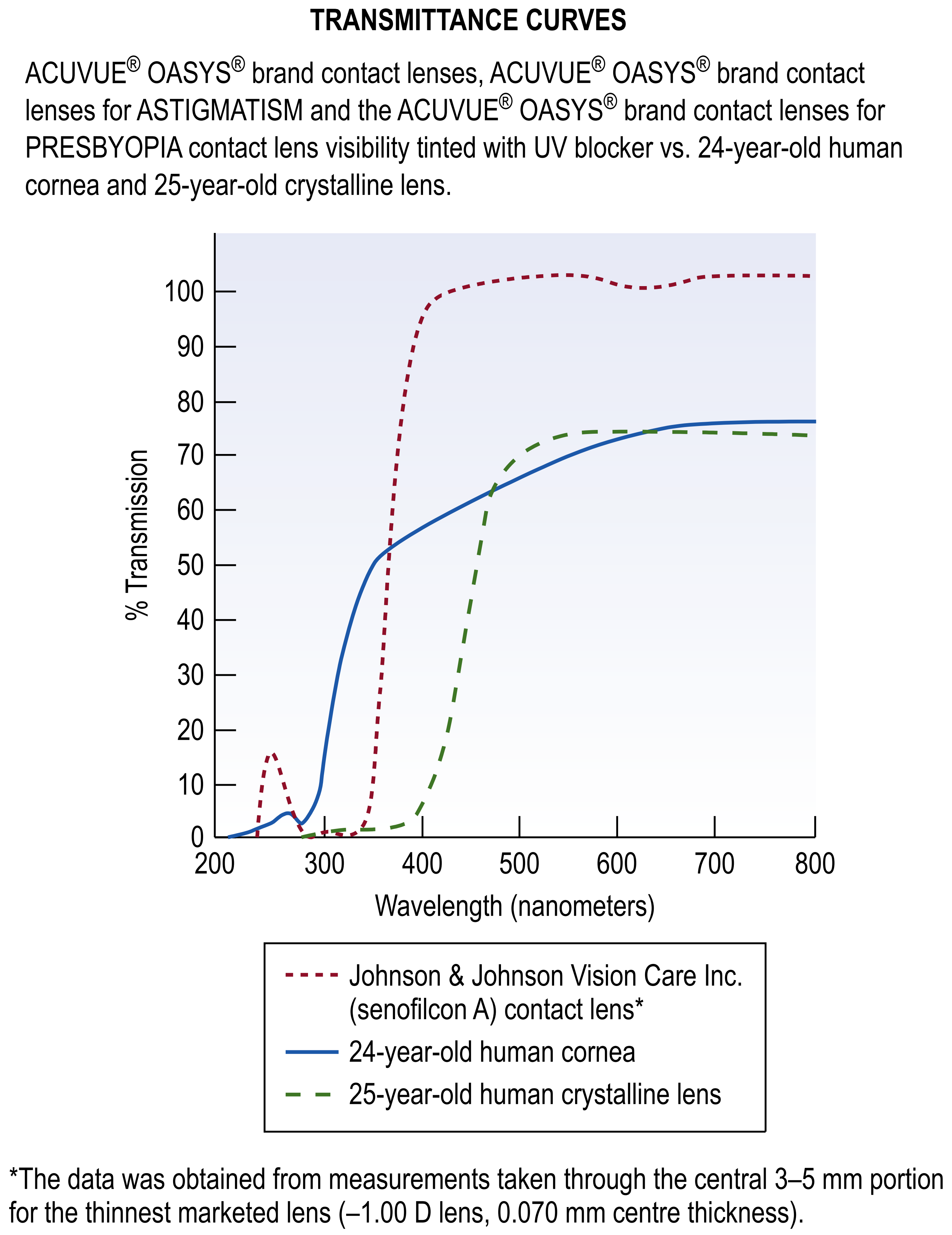

Fig. 7.17 Spectral transmission curve for soft lens with UV blocker. (From: ACUVUE® OASYS® Brand Contact Lenses with HYDRACLEAR® PLUS Technology, with permission.)

2000; Moore and Ferreira, 2006; Rahmani et al., 2014). Measurements with and without the lens in the cuvette allow for the subtraction of known lens-related factors affecting the light transmission (Quesnel et al., 2001). While there is no standard for the minimum luminous transmittance, unworn lenses are expected to fall within a ±5% tolerance band of the specified value. Specifications are provided with the packaging insert for all FDA-approved lenses. For contact lenses that claim ultraviolet (UV) light absorption, the transmittance must be less than 1% for UVB (280–315 nm) and less than 10% UVA (316–380 nm) for all class 1 absorbers. For class 2 absorbers, the respective values are 5% and 50%. A typical spectral transmittance graph for a soft contact lens with class 2 UV blocker is shown in Fig. 7.17.

UV blocking is not to be confused with handling tinting. Although the tint reduces the transmittance in the blue wavelength region by a small amount, its sole purpose is to increase visibility for better lens handling and not to provide protection against UV exposure.

Although measurement of luminance transmittance is generally confined to manufacturers and research laboratories, there is one application for which clinicians may benefit from this information. It has been shown that deposits or biofilms forming on worn lenses affect the spectral transmission (Osuagwu et al., 2014). By measuring worn lenses, information on the type and amount of deposits can be obtained.

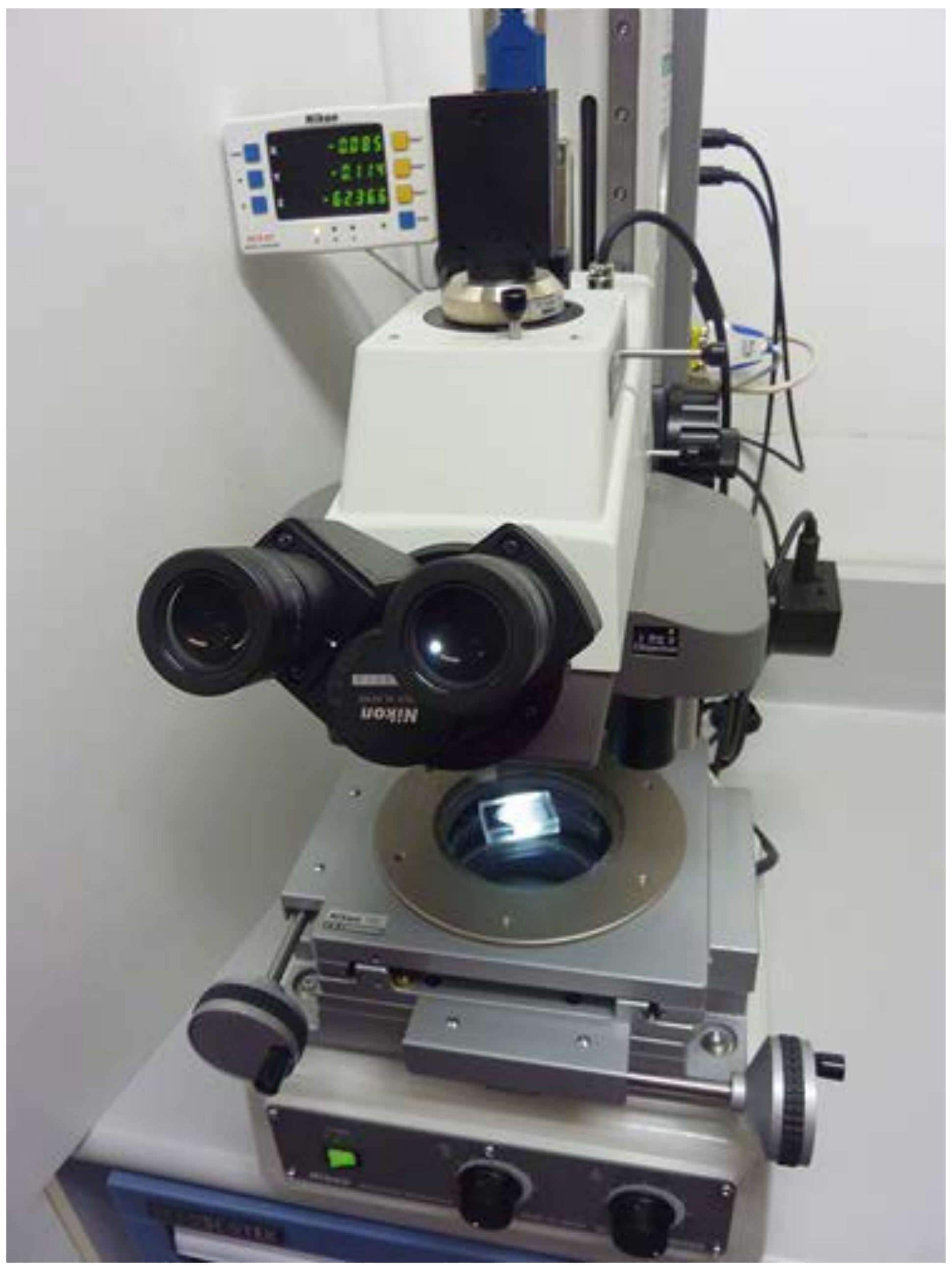

Fig. 7.18 Measuring microscope with 1 μm resolution for linear x, y and z stages. (Courtesy of Nikon.)

Lens Geometry

In the early days of soft contact lenses (1970–1990), many manufacturers would lathe cut lenses individually according to the design specification of the contact lens fitter. A range of diameter, sag, thickness, base curve and edge parameters could be combined to generate an optimized custom-fitted lens design. Careful inspection was advised, as manufacturing sometimes lacked the precision to produce the ordered lens shape. With the introduction of mass-produced frequent replacement lenses in the late 1980s, a 'one size fits all' (in some cases two sizes) approach was taken whereby the manufacturer selects the shape parameters that provide acceptable fit and comfort to the majority of patients. Mass production shifted the measurement burden to the manufacturers, as they have the obligation to comply with regulatory and ISO standards. Nonetheless, the practitioners may still want to check certain lens parameters if they observe inadequate lens fit, vision or comfort to ensure that this is not due to a poorly manufactured lens.

DIAMETER

The outside lens diameter is one of the easiest dimensions to measure. On-eye measurement can be performed using a slit-lamp biomicroscope fitted with a measurement graticule. In industry, one of the most commonly used instruments is the Optimec Model JCF (Malvern, UK). When using this instrument the lens is floating in a temperature-controlled wet cell and its plane view is projected under magnification onto a screen fitted with a ruler. The accuracy of this instrument is specified to be ±0.025 mm. For more accurate measurement, profile projectors or measuring microscopes like the Nikon MM400 (Fig. 7.18) can be used. The resolution and accuracy of this instrument can be as good as ±2 μm (Gundel et al., 1993). Most of the power-mapping instruments mentioned above also have an option to extract the lens diameter based on the captured image from the lens centration camera.

Besides the outside diameter, the diameter of the optic zone can also be of interest. This diameter is usually not visible by normal projection or observation, and either power-mapping instruments or instruments based on the knife-edge method (Ho and Ehrmann, 2000) need to be employed.

SAGITTAL DEPTH

Sagittal depth or sag is the height of a contact lens as measured as the vertical distance from the lens edge to the apex of either the front (front sag) or the back (back sag) surface. With projection instruments like the Optimec JCM, sag is measured by placing the lens in a wet cell and projecting a side elevation onto a screen with a vertical ruler. It is difficult to see the apex of the back surface of the projected image, so front sag is measured and back sag is determined by subtracting the centre thickness from the front sag. Back sag can be measured directly by using a mechanical, ultrasonic, optical or electrical probe to determine the height of the posterior apex.

The lens can be either resting on its edge, for measurements of total sag, or placed on a cylindrical support that is smaller than the lens diameter. For the latter, the diameter of the support needs to be reported with the sag value. The back sag value in itself is of little clinical interest. The main reason for its measurement is to calculate the back optical zone radius or the average base curve of a lens in combination with the respective diameters.

THICKNESS

Thickness measurements and presentations can range in complexity from a single point, through a line graph, up to thickness maps. Of most interest is the centre thickness of a contact lens. It varies with lens power and manufacturers usually specify its value for a −3.00 D lens. Centre thickness values for soft contact lenses can range between 50 µm and 250 µm, depending on power, material and lens type. The corresponding ISO tolerances are between 15 µm and 28 µm, necessitating precision instrumentation to achieve reliable measurements. Thickness can be measured by mechanical, optical or acoustic methods. For the last of these, ultrasonic pachymeters have been applied to measure contact lens thickness on-eye by taking the difference of thickness readings with and without the lens on the cornea. The accuracy of this method is affected by the assumptions made on the sound velocity in the specific contact lens material (Bachman, 1993). A similar issue arises with optical instruments. The measured optical thickness needs to be converted to physical thickness by dividing the measured value through the refractive index of the lens material. Three types of instruments can readily be applied to measure the centre thickness of soft contact lenses in vivo. Most confocal microscopes have a Z-scan option, providing intensity peaks at the air–lens and lens–cornea interface. Low-coherence interferometry instruments like the IOL Master (Zeiss, Germany) or the Lenstar (Haag Streit, Switzerland) are designed to measure ocular length, but have sufficient resolution to measure also the centre thickness of contact lenses (Rohrer et al., 2009). Optical coherence tomography (OCT) instruments are based on the same interferometric principles. With two scanning mirrors, anterior segment OCTs can scan the entire corneal area and generate thickness maps of lenses and corneas (Tao et al., 2013). Instruments such as the RTVue (Optovue, Fremont, CA, USA) can achieve a thickness resolution of less than 5 µm (Reinstein et al., 2012).

Because of the issues related to converting measured to physical thickness and the limited resolution of these two methods, the gold standard in centre thickness measurements is still the electromechanical thickness gauge. Resolution and accuracy of ±2 µm can easily be achieved; however, the measurement force needs to be carefully controlled to avoid squashing the lens. ISO 18369-3 limits the measurement force to 15 mN. The Rehder thickness gauge (Rehder Development Company, W. Lafayette, IN, USA) is one such instrument that complies with the standards and is commonly used by manufacturers and research laboratories. Misalignment of the centre of the lens of the lens is another factor that can lead to significant measurement errors, in particular for high-plus or -minus lenses, or lenses with unwanted or wanted prism in the optic zone, such as prism ballast toric lenses.

For rotationally symmetric lenses, the cross-sectional thickness profile can be of interest for the lens designer, clinician and manufacturer. A coarse resolution thickness profile can be obtained using the thickness gauge and displacing the lens from the centre in fixed increments. The Rehder thickness gauge can be fitted with a ball anvil adaptor that rotates the lens under the measurement pin. As a destructive method to obtain qualitative information on the lens thickness profile, cross-sectional slices can be cut from a lens at a selected meridian angle and placed on a microscope or profile projector. When measuring and plotting peripheral thickness, one has to distinguish radial from axial thickness. Axial thickness is a thickness measured parallel to the geometrical axis of the lens. Radial thickness refers to the thickness measured along a radius line that passes through the centre of the base curve and is thereby approximately perpendicular to the back surface (Fig. 7.19). The relationship between axial and radial thickness is given in Eq. 7.3:

$$t_{\text{radial}} = t_{\text{axial}} \times \cos\alpha \qquad \text{Eq. 7.3}$$

or:

$$t_{\text{radial}} = t_{\text{axial}} \times \cos\left(\sin^{-1}\frac{y}{\text{BC}}\right) \qquad \text{Eq. 7.4}$$

Thickness profiles are an effective method to check for unwanted lens prism. This is a common manufacturing problem for spherical lenses. However, with only one cross-section it is unlikely that the maximum lens prism will be detected.

New instrumentation is commercially available that can measure entire thickness maps of soft contact lenses with high precision. The ptychography method utilized in the Phasefocus Lens Profiler (Phasefocus, UK) provides a thickness sensitivity of ±50 nm and a lateral resolution of 7 µm (Rodenburg, 2011; Plainis et al., 2013). The OCT-based ENVISU S4410 instrument from Bioptigen (USA) has a lower resolution, but the advantage of being able to also measure radii of curvatures of front and back surfaces. Besides detecting lens prism, the most useful applications for these instruments is the measurement of the rather complex geometry of toric lenses. Progress in design and manufacturing techniques have created lens geometries with optimized clinical performance, requiring equally advanced measurement methods to ensure consistent product quality. A typical radial thickness map generated from the Phasefocus measurement output of a prism ballast toric lens is shown in Fig. 7.20. Other applications include the conversion of thickness

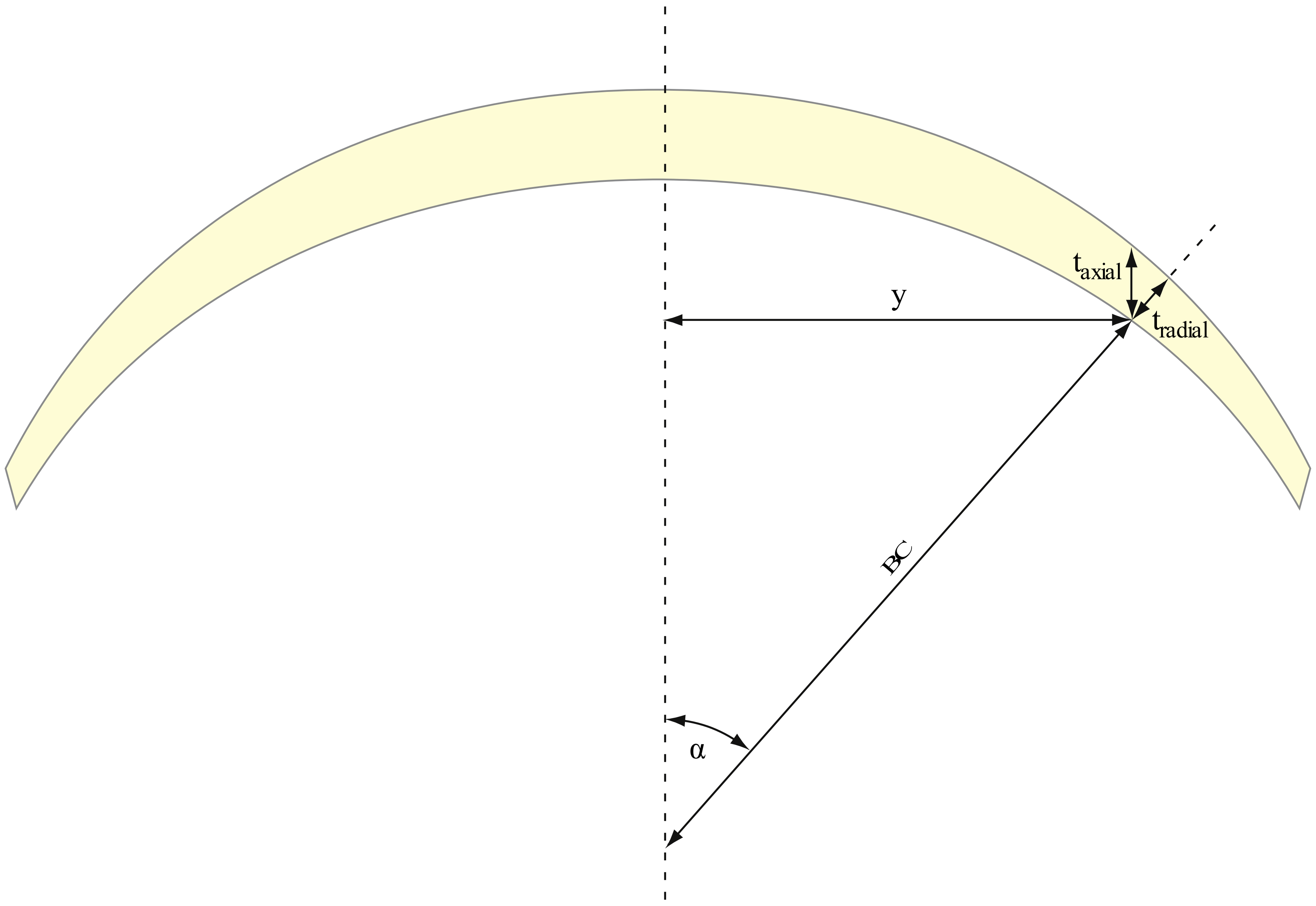

Fig. 7.19 Relationship between axial and radial thickness.

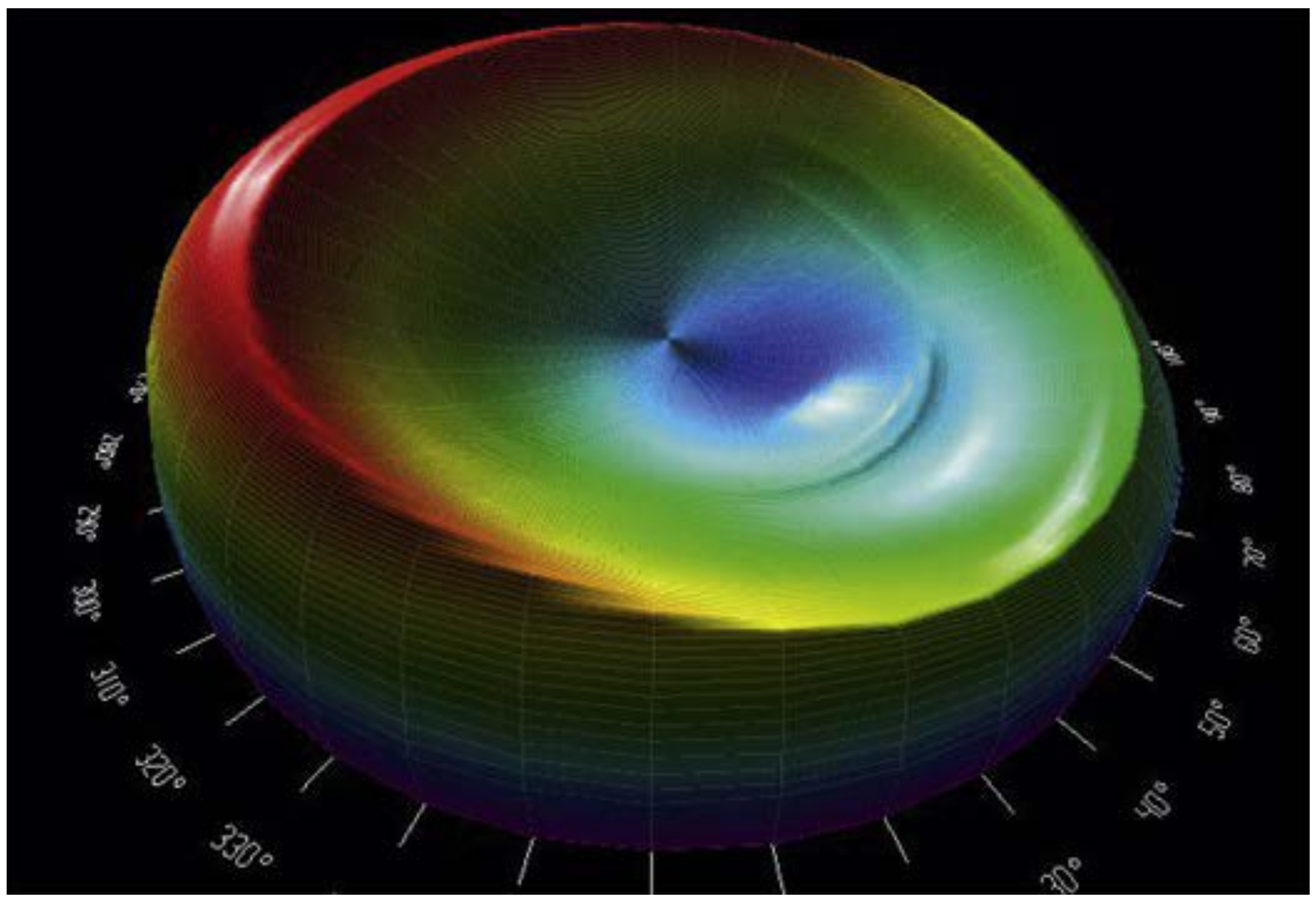

Fig. 7.20 3D thickness map of a prism ballast, soft toric lens.

maps into Dk/t maps, indicating the oxygen transmissibility through certain areas of the lens.

RADIUS OF CURVATURE

The three most commonly referenced radii of curvature on a soft contact lens are the front optic zone radius (FOZR), the back optic zone radius (BOZR) and the averaged base curve (BC) of the back surface. Of these, the FOZR is of interest only for the lens designer. For a fixed back surface, the FOZR determines the sphere power of a contact lens and can therefore be derived from power measurements.

Keratometers have been designed to measure the convex curvature of corneas, but can be used to measure the concave BOZR after some slight modifications, as illustrated in Fig. 7.21. The lens is placed edge down in a wet cell on top of a 45° prism. The prism projects the mires upwards onto the back optic zone from where they are reflected and aligned with the target lines by adjusting the radius dial. For toric back surfaces, two readings perpendicular to each other need to be obtained to acquire the steep and flat meridian. Reliable measurements may not always be possible, in particular for lenses with a low refractive index or where front and back surface curvatures are similar and mires can overlap (Holden, 1977). The keratometer takes its readings based on the surface slopes at two points, approximately 3 mm apart. Not only does this make the measurements susceptible to local variations in the surface slopes, but it also effectively provides only the central curvature for aspheric surfaces.

The 'sag' method measures and calculates the average radius of curvature for a specified diameter. Based on the circle segment in Eq. 7.5 the radius of curvature r can be calculated from the measured sag s (see also Fig. 7.22) at a specified diameter y:

$$r = \frac{s}{2} + \frac{y^2}{8 \times s} \qquad \text{Eq. 7.5}$$

Many modern lens designs have aspheric curvatures on the front and/or back surface, usually of elliptical shape. The term 'radius' is therefore inadequate to describe the actual shape of the surface. Either it is used as the central radius in conjunction with the shape factor p of the ellipse, or it corresponds to the average radius of curvature over a certain diameter. There is some ambiguity on the suitable choice of diameter. ISO 18369-3 only specifies a minimum diameter of 8 mm and gives an example with 10 mm. The Optimec JCF instrument uses also 10 mm diameter for the lens support cylinder, whereas the SHS Ophthalmic OmniSpect (Optocraft, Erlangen, Germany) measures sag over the full lens diameter. For the contact lens fitter, the most relevant parameter is the base curve radius measured over the full lens diameter, which is around 14.0 mm for most soft lenses. The Envisu S4410 (Bioptigen, Morrisville, NC, USA) is one of the few instruments that can measure the exact shape of the complete back and front surface in vitro. Spherical or elliptical surfaces can then be fitted over any selected area and the relevant

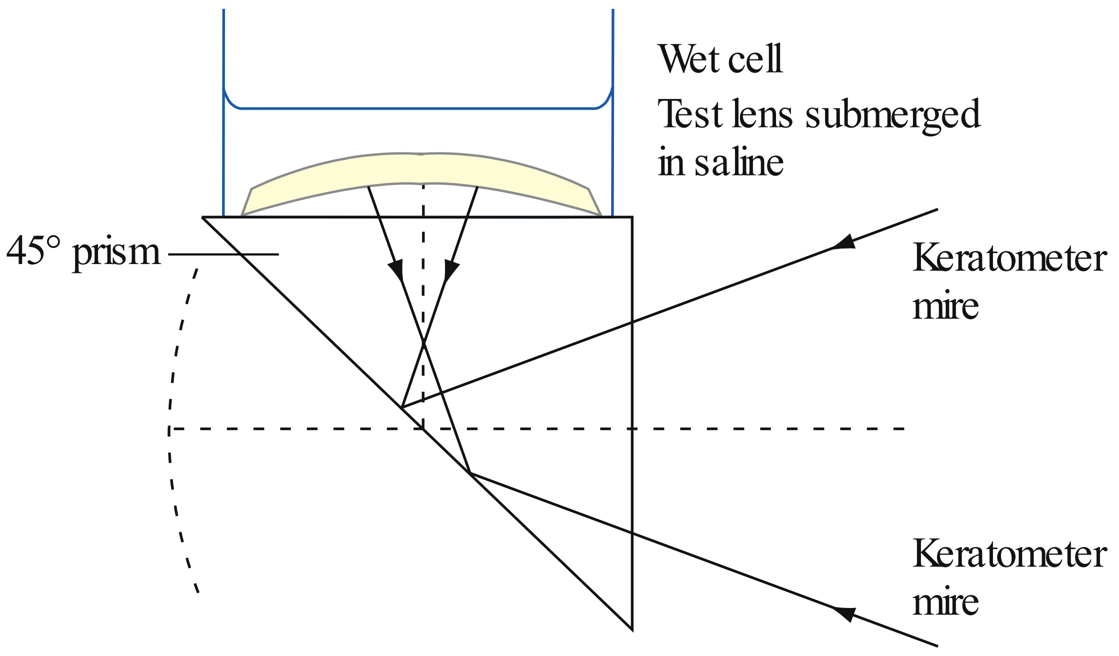

Fig. 7.21 Keratometer fitted with prism and wet cell for base curve measurements.

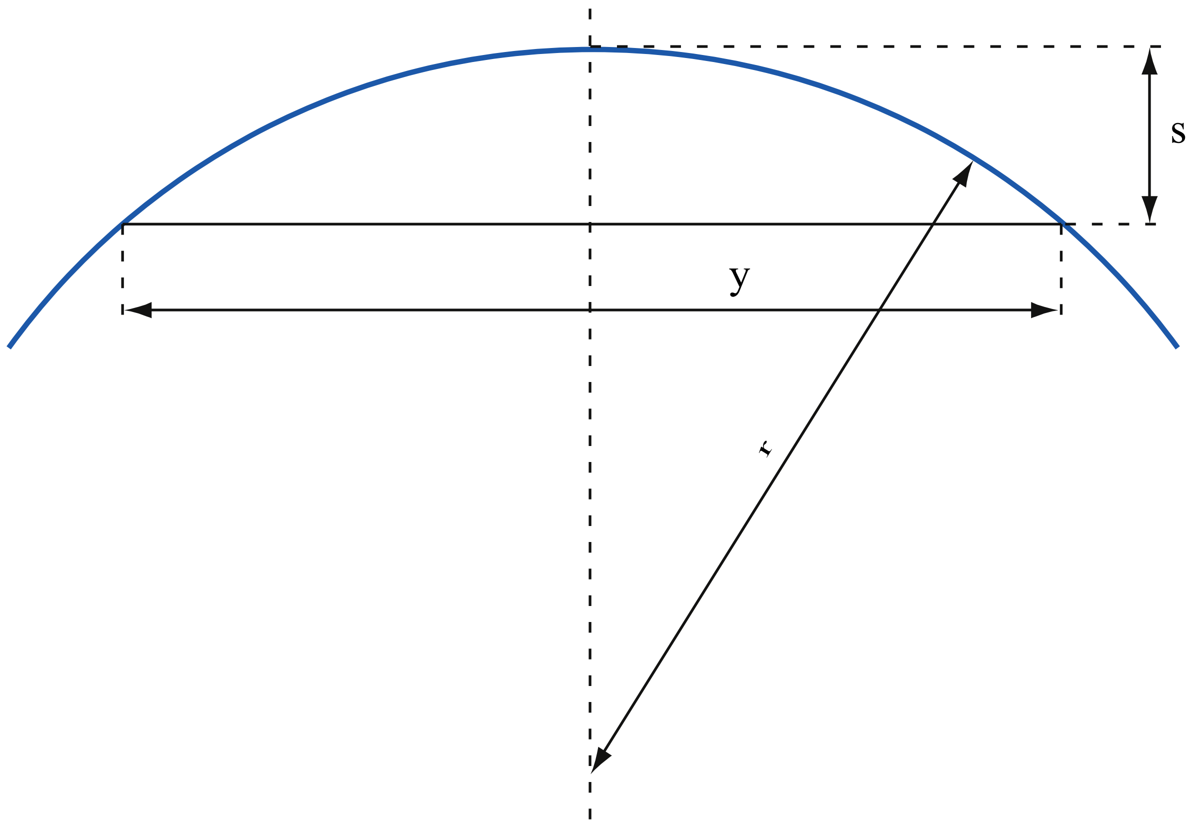

Fig. 7.22 Relationship between curvature, sag and diameter.

radii and shape factors extracted. In optometry, surfaces with conic cross-sections are described by the central radius of curvature r_0 and the conic constant p, as defined by Eqs. 7.6 and 7.7:

$$p = \left(\frac{b}{a}\right)^2 \qquad \text{Eq. 7.6}$$

and:

$$r_0 = \frac{b^2}{a} \qquad \text{Eq. 7.7}$$

where a = major axis of ellipse and b = minor axis of ellipse.

The value of p identifies the five types of conic sections:

Ellipsoid	$p > 1$
Steepening towards the periphery:	
Sphere	$p = 1$
Ellipsoid	$0 < p < 1$
Flattening towards the periphery:	
Paraboloid	$p = 0$
Hyperboloid	$p < 0$

An approximate value for the shape factor can be obtained by measuring the central curvature r_0, the lens diameter LD and the back sag, and applying Eq. 7.8:

$$p = \frac{2 \times r_0}{\text{back sag}} - \frac{\left(\frac{LD}{2}\right)^2}{\text{back sag}^2} \qquad \text{Eq. 7.8}$$

In addition to the average base curve, the shape factor gives lens designers another degree of freedom to optimize the back surface shape to achieve optimized on-eye fit and comfort.

EDGE

The edge of a contact lens describes the transitional area between the front and the back surface around the perimeter of the lens. The two major aspects of edge inspection are assessment of the cross-sectional edge profile and the detection of edge defects around the circumference. For the latter, the inspection can be non-destructive if the lens is viewed in a wet cell from above, under magnification. Most disposable soft lenses undergo a 100% edge defect inspection before being packaged. Inspection is either manually or with the assistance of video capturing and image analysis. Typical defects include edge flashing, tears and notched edges (Fig. 7.23).

The cross-sectional profile of soft lens edges can significantly influence the on-eye performance, particularly with respect to comfort and staining (Efron and Veys, 1992; Young et al., 1993; Maissa et al., 2012; Ozkan et al., 2013; Wolffsohn et al., 2013; Maki and Ross, 2014). Although there is still some dispute over what comprises the optimal edge shape (Maissa et al., 2012), poorly manufactured or designed edges have often been implicated in inferior comfort (Phillips and Stone, 1989; Jones et al., 2013). Confocal microscopy, OCT imaging and other optical methods have been attempted to visualize the edge profile non-destructively in vivo and in vitro. Of these methods, high-resolution OCT imaging is used most widely to capture the edge shape (Fig. 7.24); however, the resolution is insufficient to obtain accurate quantitative parameters.

Improved results can be achieved with the destructive 'edge-slicing' method. In this, the contact lens is pressed flatly on a sheet of plastic. Two razor blades are held together so that their cutting edges are lined up parallel. Cutting through the centre of the lens, a thin cross-sectional slice is obtained. A second cut, perpendicular to the first one, provides an additional two slices. These slices are placed in a saline-filled wet cell or petri dish for observation under a microscope or profile projector (Fig. 7.25). Edge profile images can be captured and edge thickness measurements can be taken at a prescribed distance from the apex. From the four slices, a good estimation can be obtained on the amount of edge prism.

Edge shapes are commonly classified into three edge types (Fig. 7.26) (Maissa et al., 2012): round edge, knife edge and chisel edge. For the clinician, the apex location may also be of interest as it may adversely affect the interaction with either the eyelids or the conjunctiva. The apex location can be given as a relative measure of the edge thickness or as an absolute value equivalent to the edge lift as shown in Fig. 7.27.

Conclusion

The measurement of soft contact lenses covers a wide range of optical, mechanical, geometrical and surface parameters and generally requires sophisticated equipment and expertise to achieve reliable results. With the widespread use of mass produced, daily disposable lenses and the tightening of quality assurance and regulatory requirements, the measurement responsibilities are now predominantly in the domain of the contact lens manufacturers. It is in the interest of manufacturers to undertake accurate and comprehensive measurements to ensure a consistent product quality and avoid costly product recalls, while also achieving a high production yield.

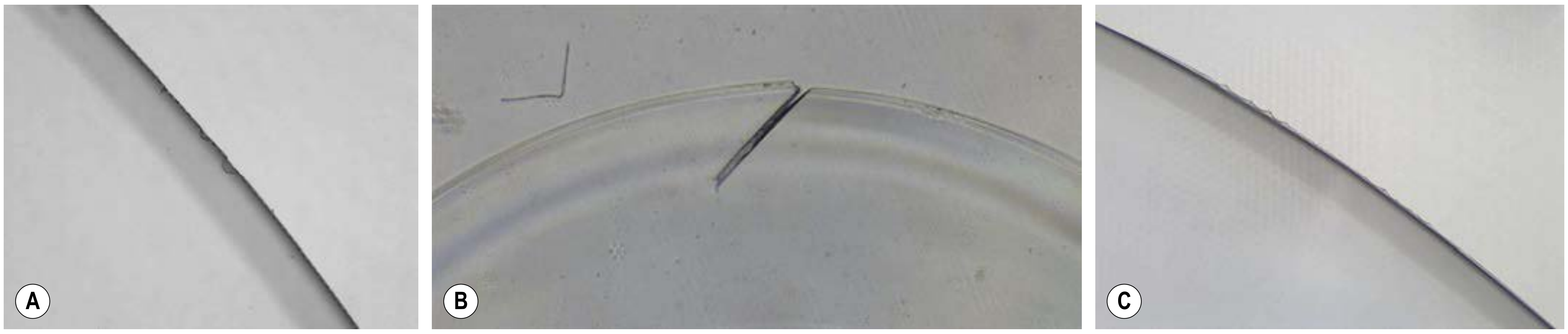

Fig. 7.23 Typical edge defects: (A) notch; (B) tear; (C) flashing.

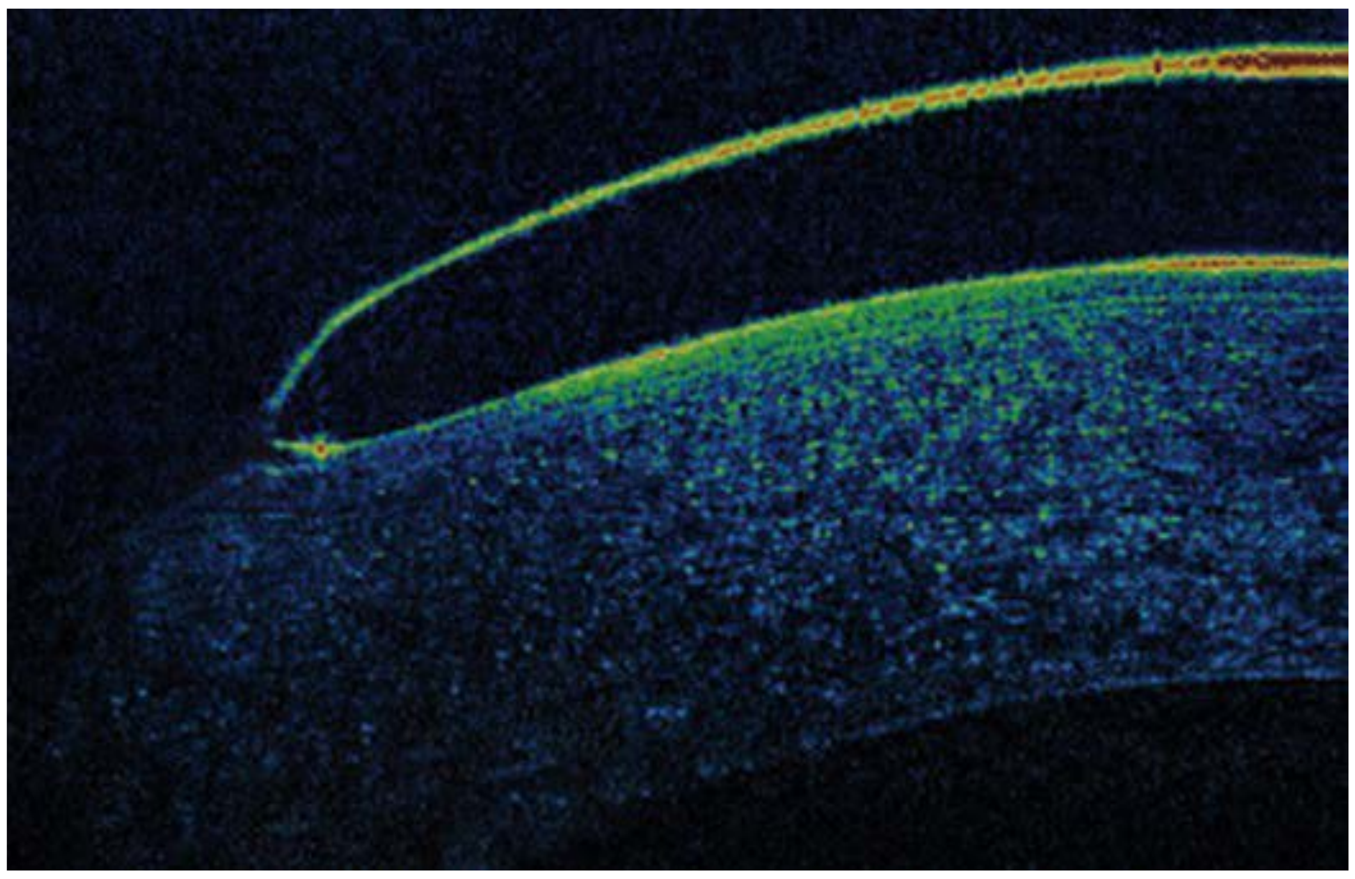

Fig. 7.24 Cross-sectional edge profile obtained by in vivo OCT imaging. (Reproduced with permission from Kaluzny, B. J., Kaluzny, J. J., Szkulmowska, A. et al. (2006). Spectral optical coherence tomography: a new imaging technique in contact lens practice. Ophthal. Physiol. Opt., 26, 127–132.)

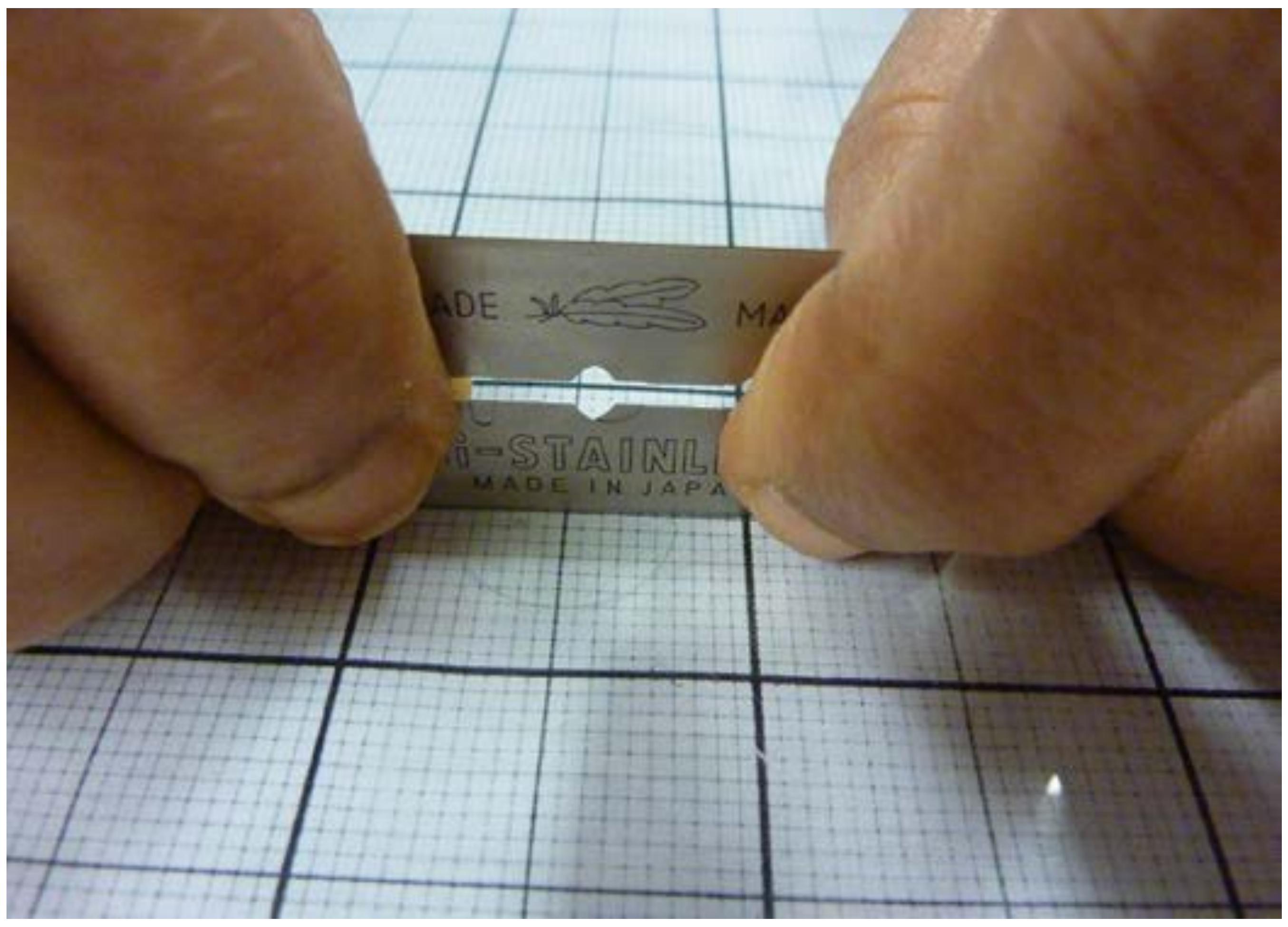

Fig. 7.25 Edge slicing with two razor blades. (Courtesy of Feather Razorblades.)

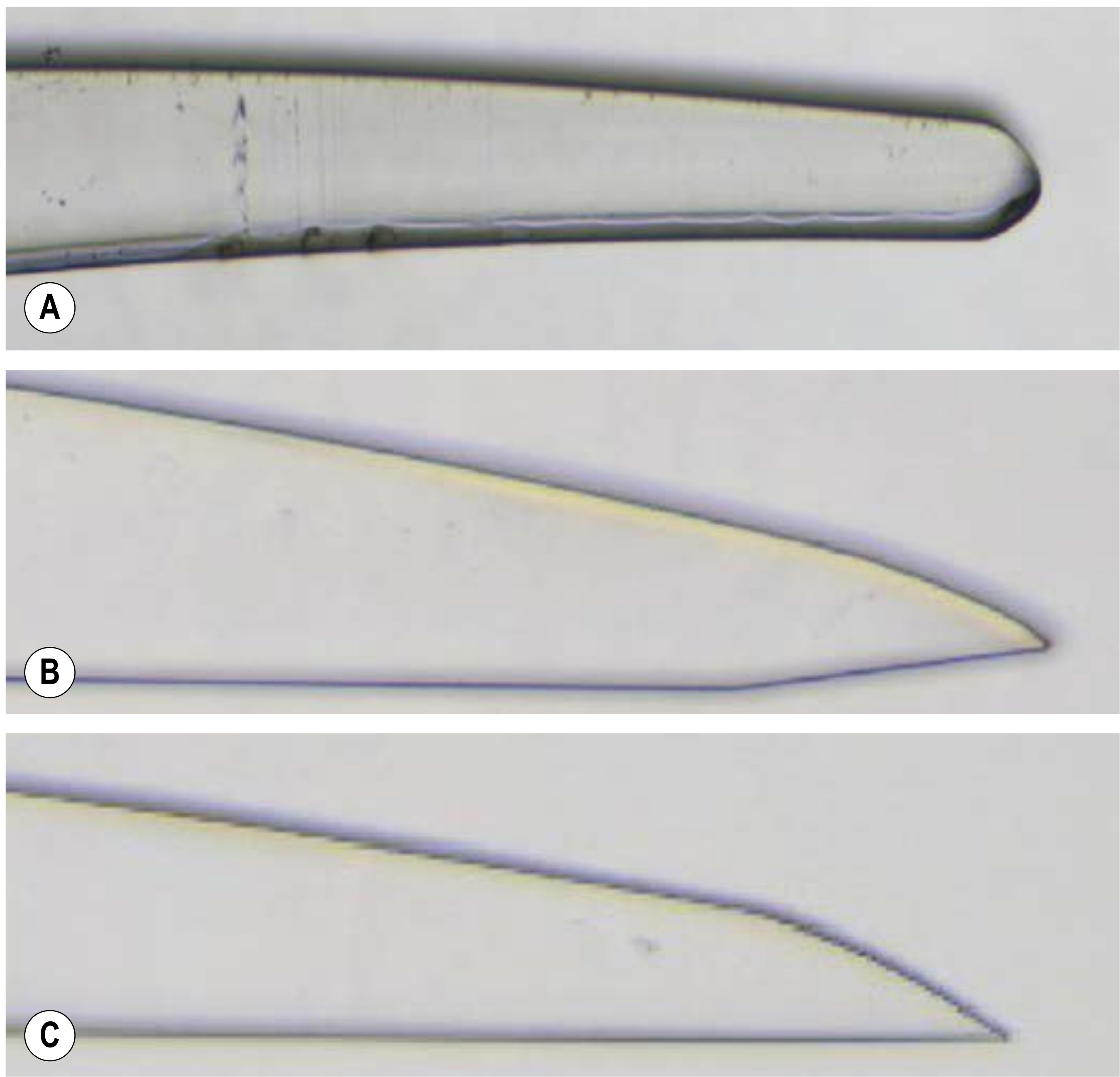

Fig. 7.26 Three soft lens edge types: (A) round; (B) knife; (C) chisel.

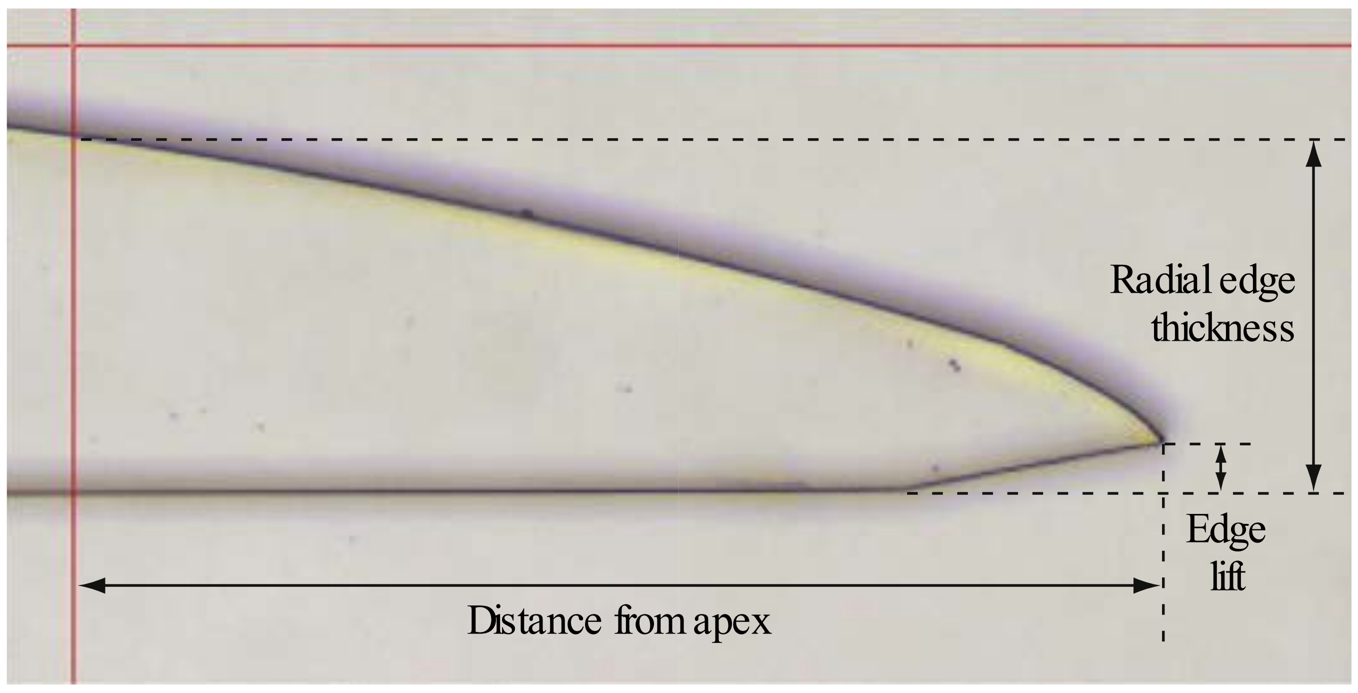

Fig. 7.27 Edge profile parameters.

Practitioners may still want to check certain parameters if they observe otherwise-unexplained poor on-eye performance. A number of suitable tools are available in most practices to confirm or exclude suspected lens defects. Research laboratories often develop their own instrumentation to effect more accurate measurements of specific lens parameters and properties; however, there are still a number of properties, particularly in relation to in vivo measurements, that elude accurate quantification. Among them on-eye dehydration, dynamic friction and tear film behaviour. Even more difficult to measure are the functional effects and their correlation with certain lens parameters, such as edge–lid interactions or lens-induced corneal pressure points, as they are highly dependent on individual ocular conditions.

Access the complete references list online at http://www.expertconsult.com.

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8

Soft Lens Design and Fitting

GRAEME YOUNG

Introduction

Assessment of soft contact lens fit is probably the most commonly undertaken task in contact lens practice but is also one of the least discussed, possibly because it is regarded as a relatively straightforward exercise. However, soft lens fitting is not just a process of finding a soft lens that fits but also one of determining the soft lens and wearing regimen that will provide the patient with the most comfortable, convenient and safe contact lens wear.

There is a traditional view that fitting soft lenses is a less technically challenging option than that of fitting rigid lenses; however, the increased choices of materials, wearing regimens, care systems and lenses themselves make the decision-making process as complex for soft lenses as rigid lenses. Since these decisions rely on clinical judgement rather than measurement, soft lens fitting, when done well, is a skilled activity.

Ocular Measurement

Contrary to popular belief, keratometry is of little help in the fitting of soft lenses because the curvature of the central cornea is only one of a number of relevant ocular parameters governing soft lens fit. Normal variations in corneal asphericity and diameter have as much effect on corneal geometry (e.g. sagittal height) as the normal variation in corneal curvature (Young, 1992, 2014). Thus keratometry alone is a poor predictor of the optimum soft contact lens base curve radius. As there is a positive correlation between corneal diameter and corneal curvature (i.e. a tendency for flatter corneas to be larger in diameter), any change in sagittal height due to varying corneal radius is nullified by corresponding variation in corneal diameter (Garner, 1982). This would suggest that corneal asphericity is the most important determinant of soft lens fit.

One caveat applies, however, with atypical combinations of corneal diameter and curvature, which may indicate extremes of sagittal height. For instance, a large cornea showing a relatively steep keratometry measurement is likely to have a relatively large sagittal height and will probably require a soft contact lens with a correspondingly large sagittal depth (i.e. steep). Conversely, a small flat cornea is likely to have a small corneal sagittal height and require a relatively flat base curve. When viewed from the side, these corneas often seem abnormally deep or shallow, even to the naked eye.

Measurement of the horizontal visible iris diameter (HVID) provides a useful guide to whether a large or small lens is required. However, this is only a rough indicator because the true corneal diameter is significantly larger than the iris diameter. The horizontal corneal diameter has been shown to be, on average, 1.5 mm larger than the HVID (Martin and Holden, 1982: Hall et al., 2013). This can be measured to the nearest half-millimetre with a pupillary distance (PD) rule or, more accurately, using a slit-lamp graticule.

Palpebral aperture does not have the same relevance as in the fitting of rigid lenses, but extreme cases are worth noting. A narrow palpebral aperture may increase difficulties of insertion and so, given the choice, a smaller lens may be appropriate. Larger palpebral apertures are often associated with incomplete blinking. This might influence the choice of lens material, particularly when noted in combination with signs of corneal desiccation staining.

Basic Principles

FORCES ACTING ON A SOFT LENS

A range of forces act on a soft lens, keeping the lens in place on the eye but allowing it to move a small amount between blinks (Fig. 8.1).

Soft lenses are required to flex in two directions in order to align to the shape of the cornea and sclera. As soft lenses are usually flatter than the central corneal curvature, they steepen in order to align with the cornea but flatten and stretch at the periphery so as to align with the sclera. A useful model is to envisage the lens periphery as a series of concentric elastic bands that stretch in order to align with the peripheral ocular shape (Kikkawa, 1979). When a large amount of peripheral stretching is required, this results in a tight fit. Conversely, when the lens is relatively large and there is no stretching, the lens is relatively loose and may even show edge stand-off.

The stresses formed in the lens are proportional to the mechanical properties of the material as well as the dimensions of the lens. Due to the viscous nature of the tear fluid, this deformation of the lens to match the shape of the eye results in pressures being developed in the post-lens tear film that Martin and Holden (1986) have termed 'squeeze pressure'. This squeeze pressure is related to the amount of force required to move the lens across the eye and therefore lens fit (Martin and Holden, 1986; Martin et al., 1989). The amount of force required to move the lens is also related to the viscosity of the post-lens tear film (Martin et al., 1989) and this helps to explain why the soft lens movement can vary markedly during a given wearing period.

Soft lens retaining forces are relatively large compared with those of rigid lenses and therefore gravitational force has less of an effect.

IDEAL SOFT LENS FIT

The appropriate soft lens, as far as possible, should be indiscernible to the patient during wear. In other words, there should be no discomfort or disturbance of vision throughout the wearing period. Any effect on ocular physiology should be minimal and

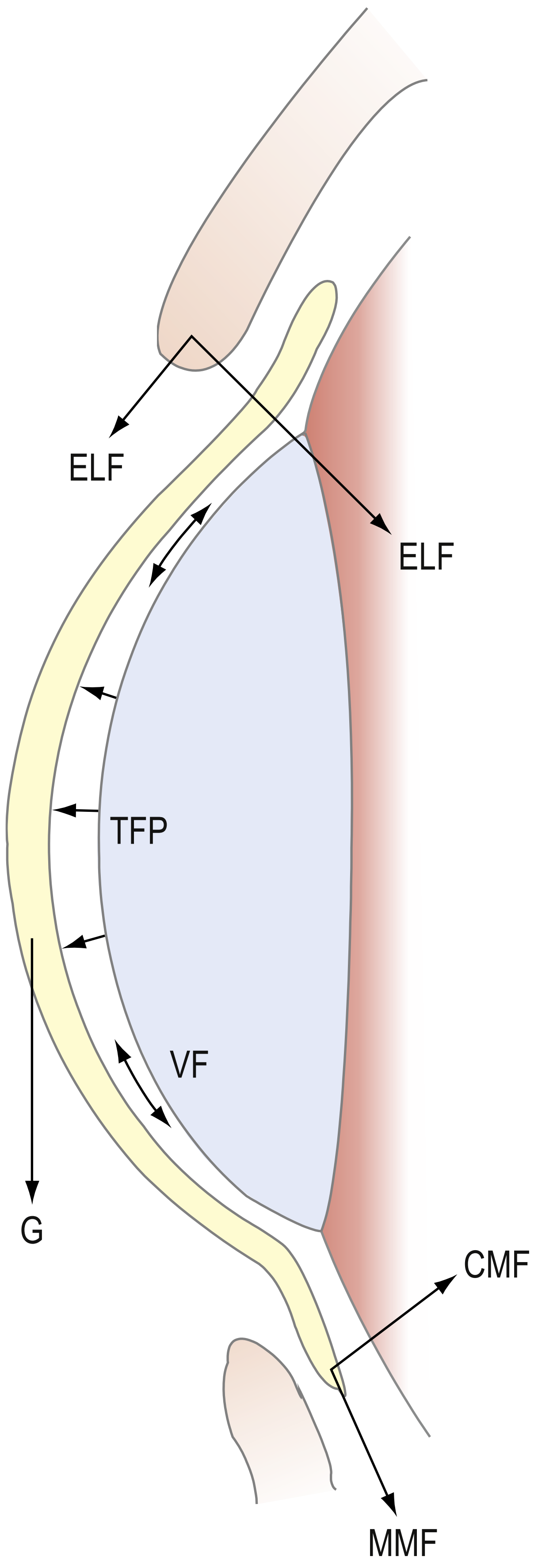

Fig. 8.1 Forces acting on a soft lens. CMF = circumferential membrane force; ELF = eyelid force; G = gravity; MMF = meridional membrane force; TFP = tear fluid pressures; VF = viscous forces. (Adapted from Martin, D. K., Boulos, J., Gan, J. et al. (1989). A unifying parameter to describe the clinical mechanics of hydrogel contact lenses. Optom. Vis. Sci., 66, 87–91.)

within acceptable limits. A well-fitting soft contact lens should fulfil the criteria listed in Table 8.1.

TABLE 8.1 Requirements of a Well-fitting Soft Lens

Requirement	Significance
Good comfort	Patient satisfaction
Constant corneal coverage	Avoidance of peripheral corneal staining Comfort
Good centration	Corneal coverage Stable peripheral vision
Movement on blink or version	Adequate post-lens lubrication Exchange of metabolic waste Avoidance of conjunctival staining
Optimum tightness on push-up	Avoidance of discomfort through excessive movement or excessive mechanical squeeze force Avoidance of adherence with dehydration Avoidance of conjunctival indentation
Good peripheral fit (i.e. alignment)	Avoidance of conjunctival indentation Avoidance of edge stand-off; comfort
Good and stable vision	Patient satisfaction

Soft Lens Design

Contact lens practitioners have little direct control over lens design. Custom-made soft lenses can be ordered from specialist laboratories; however, these are relatively expensive. Nevertheless, these can be useful for extreme prescriptions or ocular topographies that prove unsusceptible to stock designs.

Most lenses are offered in a limited range of specifications (e.g. two base curves in a single diameter). Despite the relatively wide range of corneal diameters in the population, most spherical soft lenses are specified within a relatively narrow range of diameters: 14.0–14.5 mm. The practitioner is therefore largely dependent on the judgement of the manufacturer.

The design of proprietary soft lenses is governed by a number of factors in addition to geometry, including material, method of manufacture and lens power.

LENS MATERIAL AND WATER CONTENT

The selection of contact lens material is relevant to several aspects of lens performance (Jones et al., 2013):

- oxygen transmission
- deposit resistance
- surface wetting
- rigidity (and therefore fitting characteristics)
- lubricity.

Nowadays, there is little justification for using low-Dk lenses such as poly(hydroxyethyl methacrylate) (polyHEMA) lenses. The effects of hypoxia with conventional low-water-content (i.e. <50%) lenses are well documented (Bruce and Brennan, 1990). Based on estimates of corneal swelling, complications such as corneal striae can be expected to affect a high proportion of wearers (Holden and Mertz, 1984). An exception to this rule is in those rare cases where it proves impossible to fit patients with higher-Dk products.

The prime decision, therefore, is whether to use a silicone hydrogel or conventional hydrogel material in mid- (50–60%) or high-water-content (>60%) lenses. All silicone hydrogel lenses will provide superior oxygen transmission compared with conventional lenses; however, they may incorporate disadvantages in relation to mechanical properties and surface wetting (see Chapter 4).

Comparing conventional hydrogels, a higher-water-content material does not necessarily guarantee that the lens will produce better oxygen transmissibility (Morgan and Efron, 1998). Different material categories (e.g. ionic and non-ionic) have differing strengths and weaknesses, which can be taken into account when selecting a lens type for a given patient.

Higher-water-content lenses tend to be thicker for two reasons. First, higher-water materials have a lower modulus and therefore tend to be less easy to handle in equivalent thicknesses. Second, there is a minimum thickness threshold for any material below which lenses tend to induce corneal desiccation staining. There is some variation between patients and precise material types; however, for a 70% water content material, the critical thickness is approximately 0.12 mm, whereas with mid-water lenses it would be approximately 0.06 mm.

METHOD OF MANUFACTURE

The method of lens manufacture can influence the edge design. Lathing allows a greater range of parameters, but lathe-cut lenses tend to incorporate a thicker edge design than do moulded lenses. Cast moulding is the predominant method of soft lens manufacture owing to the relatively low manufacturing costs, high reproducibility and the fact it allows thin edges to be formed.

BASE CURVE RADIUS (BACK OPTIC ZONE RADIUS)

Soft lenses are specified by base curve radius (BC), total diameter, back vertex power and material. If the lens is available in only a single specification (i.e. a one-fit lens), the lens brand name and power may be enough to specify the lens prescription. However, this apparent simplicity belies the complexity and importance of soft lens design. Lenses with apparently similar specifications can show widely differing fitting characteristics (Young et al., 1997), for instance, due to variations in back surface design (Young et al., 1993).

Traditionally, BC is the main parameter to be modified when attempting to optimize lens fit; a steepening of BC is required to tighten lens fit and vice versa. However, even with relatively thick polyHEMA lenses, large changes in BC are required in order to have a significant effect on lens movement (Lowther and Tomlinson, 1981). With thinner high-water lenses, changes in BC have even less effect. The labelled BC is therefore of little help in soft lens fitting.

BC is also not helpful when comparing different brands of lens. Lenses of similar BC can show widely differing sagittal depths because of differences in back surface design (Burki, 1997). This and differences in materials' mechanical properties means that widely differing lens fits may be observed from seemingly similar lenses. With silicone hydrogel lenses the high modulus of elasticity of many lenses means that even small (0.2 mm) changes in base curve can have a significant impact on lens fit and comfort (Dumbleton et al., 2002).

TOTAL DIAMETER

Unfortunately, the labelled total diameter is often as unhelpful as the labelled BC. The fact that the water content, and therefore the dimensions, of some lens materials varies with temperature makes it difficult to compare the labelled diameter of one lens with another. Most non-ionic lenses, particularly those containing N-vinyl pyrrolidone, shrink by approximately 0.5 mm when raised from room to eye temperature. Ionic lenses are also temperature sensitive, although they shrink much less than non-ionic lenses (Young et al., 2011). Some lenses are made larger in diameter to compensate for this.

A further complicating factor is that the on-eye diameter is affected by the sagittal depth of the lens. Lenses of similar nominal diameter can vary in sagittal depth by as much as 1 mm (Burki, 1997) and, as the periphery of a soft lens flattens to align with the scleral profile, the sagittal depth can have a significant effect on effective diameter.

BACK VERTEX POWER

Some modifications are often made to the lens design at the extremes of the power range. At the lower end of the minus power range (<−1.50 D) the centre thickness is usually increased to improve lens handling. At the higher end of the power range, the centre thickness is often reduced and the optic zone diameter kept to a minimum in order to maximize oxygen transmission.

The thickness of high-minus lenses can be further reduced and the optical performance improved by incorporating aspheric optics in order to overcome lens spherical aberration (Cox, 1990). Aspheric optics can also be incorporated to reduce the spherical aberration of the eye (Kollbaum and Bradley, 2005). A number of designs are available that claim to use aspheric optics in order to improve visual performance (e.g. Bausch & Lomb PureVision 2, CooperVision Biomedics Premier); however, the published data have given conflicting results (Morgan et al., 2005; Efron et al., 2008; Rae et al., 2009; Lindskoog et al., 2011).

With plus-power lenses, the optic zone diameter is again minimized in order to minimize centre thickness. Some manufacturers have utilized a larger diameter in order to accommodate the anticipated greater movement; however, hyperopic eyes tend to be smaller in diameter and therefore this is of doubtful benefit.

There tends to be little difference in lens fit between low-minus and higher-minus lenses of similar design. However, plus-power lenses tend to show significantly more post-blink movement than do minus lenses, which is probably due to greater interaction with the upper lid (Young et al., 1993).

CENTRE THICKNESS

Lens centre thickness is relevant to ease of lens handling and susceptibility to dehydration. Mid-water-content hydrogel lenses (50–59%) are generally manufactured with centre thicknesses in the range 0.06–0.10 mm, whereas high-water-content lenses (60%) generally have centre thicknesses in the range 0.10–0.18 mm. Silicone hydrogel lenses vary widely in water content but tend to have centre thicknesses in the range 0.07–0.09 mm.

EDGE THICKNESS AND DESIGN

Due to poor measurement repeatability, soft lens peripheral thickness is not the subject of an ISO standard and is not always routinely verified during lens manufacture. Nevertheless, variations in peripheral thickness can have a significant effect on lens fit; contrary to expectations, thicker-edged lenses often show a looser fit than do thinner lenses of similar basic design (Young et al., 1993).

Modern designs generally taper to a thinner edge than many older designs. Several edge shapes have been identified, including 'rounded', 'knife' and 'chisel' edges. The thinner knife-and chisel-edge designs appear to give better comfort, sit closer to the bulbar conjunctiva, show less movement and have less interaction with the lids than do the rounded design (Maissa et al., 2012; Wang et al., 2009).

Soft Lens Fitting Options

Many soft lenses show an acceptable fit on a wide range of eyes, but an acceptable fit is not necessarily the optimal or most comfortable fit. As well as finding the most appropriate lens design, selecting the optimal lens involves finding the lens material, lens replacement schedule and wearing regimen that best suit the individual patient. In order to achieve this, it is necessary to use a wide range of soft lens types and brands.

Trial Lens Fitting

INITIAL LENS SELECTION

As discussed earlier, without understanding the material and design characteristics of a particular lens it is not possible to predict its clinical fitting performance. Even with this information, it is difficult to predict from keratometry and HVID measurements which lens is likely to be the most suitable.

The selection of a first trial lens can take into account HVID, particularly if the cornea appears to be unusually large or small. The selection of BC is a process of trial and error unless there is useful information from the patient's previous lenses. If, for instance, the patient previously required a steeper-fitting lens in order to achieve a successful fit, this would suggest the need for a lens with relatively tight-fitting characteristics.

Lens material and wearing regimen are also key factors in the selection of the initial trial lens. Although compromises occasionally have to be made, these should be selected based on an assessment of the patient's requirements rather than on prescribing habits or practice policy.

SOFT LENS INSERTION

1. Before inserting a soft lens, place it between the index and middle fingers and rinse with saline to remove any debris.
2. Allow the excess saline to drain before placing the lens on a dry forefinger.
3. With the forefinger of the other hand, hold open the patient's top lid while holding open the bottom lid with the middle finger of the other hand (Fig. 8.2).
4. With the patient looking to the opposite side, place the lens on the bulbar conjunctiva, allowing it to stick by capillary force rather than pressure from the finger.
5. Ask the patient to look towards the lens. Continue to hold the lids open for a few seconds to allow the lens to settle.
6. Ask the patient to look down, then let go of the lids. With thin soft lenses the lens can be easily folded or dislodged if it has not properly settled.
7. If the patient finds the lens uncomfortable, this may be due to post-lens debris, in which case temporarily dislodging the lens on to the sclera may remove this (Fig. 8.3).

SOFT LENS REMOVAL

1. Ask the patient to look up.
2. Hold down the patient's bottom lid with the middle finger of the left hand.
3. Slide the lens onto the lower sclera.
4. Pinch and remove the lens with the thumb and forefinger (Fig. 8.4).

SETTLING TIME

Lenses alter their fitting characteristics during a period of equilibration owing to differences in temperature, pH and osmolarity

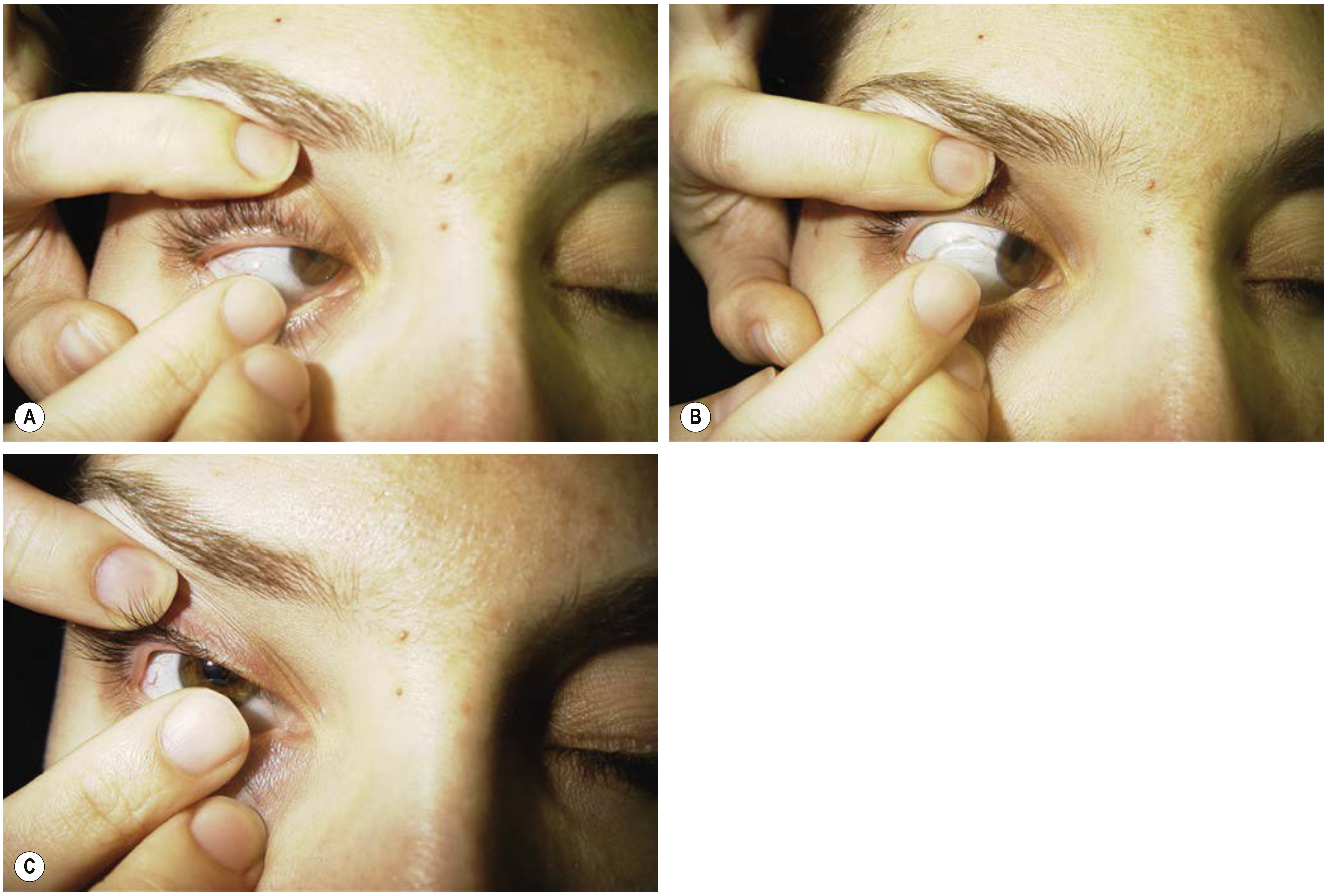

Fig. 8.2 Inserting a soft lens. (A) Direct the gaze of the patient nasally to expose the bulbar conjunctiva. Retract the upper eyelid with your left forefinger, and the inferior eyelid with the middle finger of the right hand. (B) With your right forefinger, apply the lens to the bulbar conjunctiva of the patient. (C) Slide the lens laterally on to the cornea. Once the lens is centred on the cornea, and without air bubbles beneath it, your finger can be removed. (Courtesy of Adrian Bruce.)

between the lens vial and eye. Lenses tend to show less movement after this period of settling. In some cases, lenses exhibit gross tightness immediately after insertion and are unlikely to show sufficient improvement on settling. The post-lens tear film appears to settle within minutes, whereas the pre-lens tear film can take 30 minutes to thin to its equilibrium state (Nichols and King-Smith, 2004). A fast blink rate appears to quicken lens settling (Golding et al., 1995), possibly because the thickness of the post-lens tear film is an important factor in lens movement (Little and Bruce, 1994).

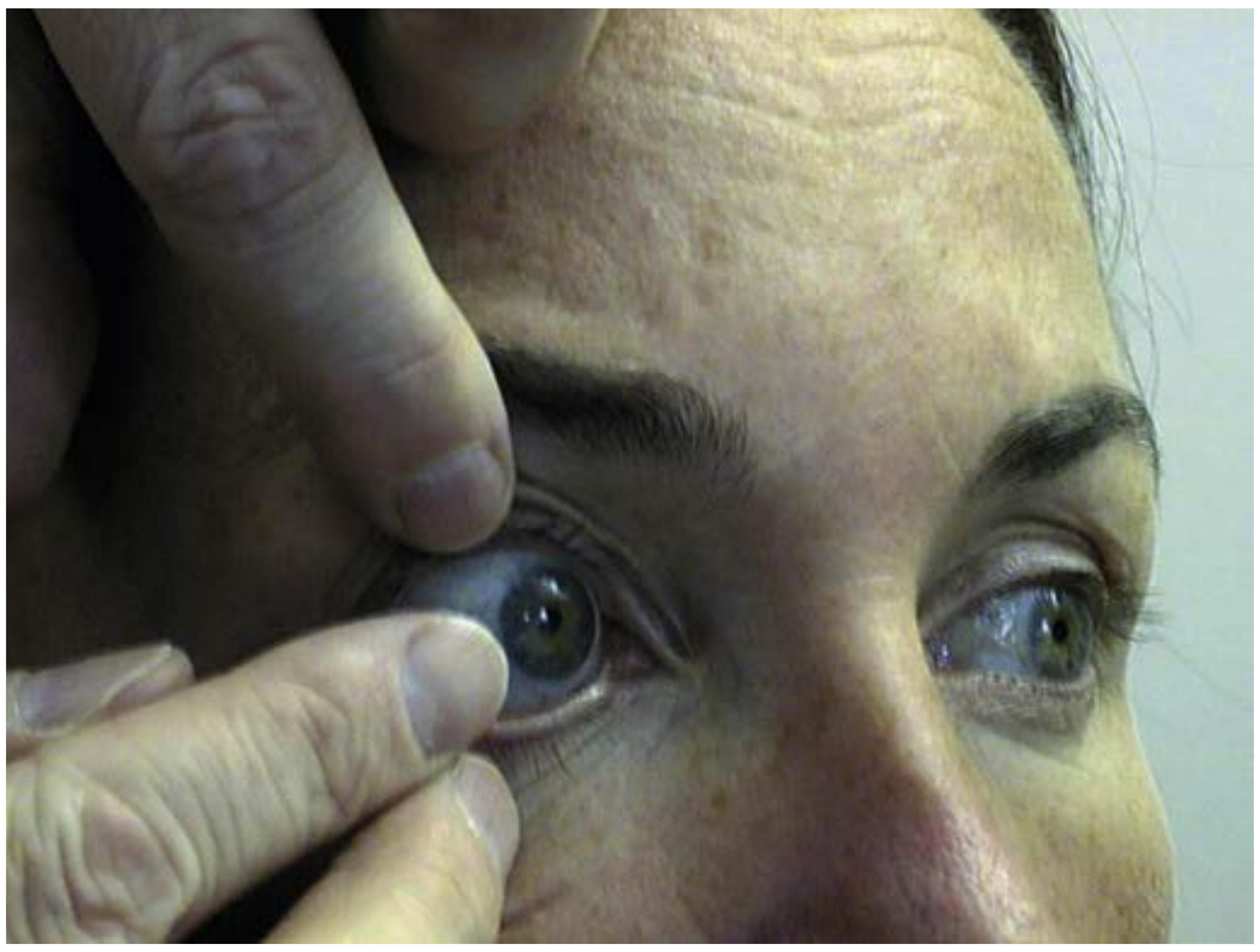

Fig. 8.3 Displacing a soft lens to dislodge a foreign body.

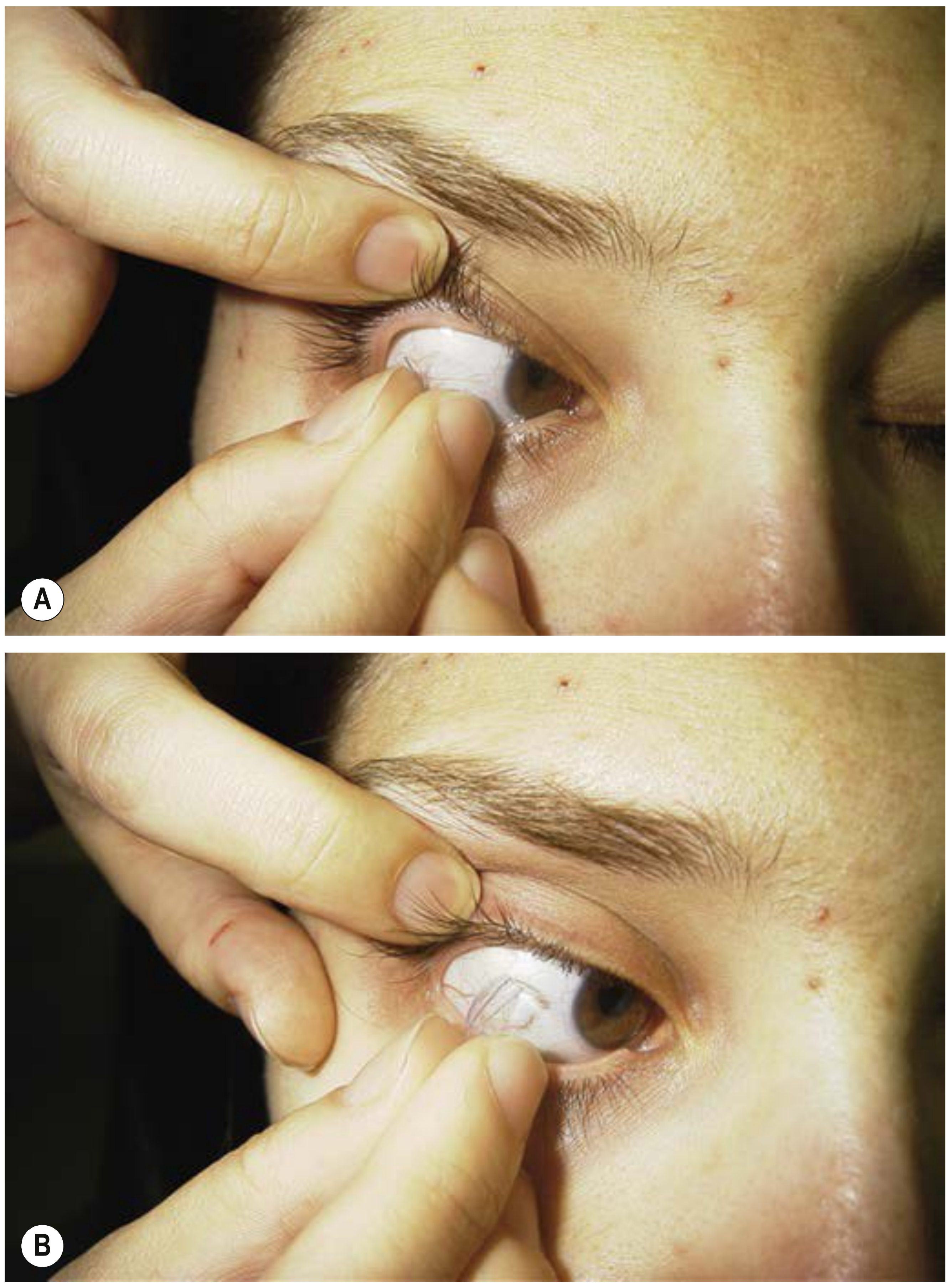

Fig. 8.4 Removing a soft lens. (A) The lens is slid off the cornea on to the inferior or temporal bulbar conjunctiva and light pressure is applied on to the lens surface using the thumb and forefinger. (B) The fingers are pinched together to lift the lens off the eye. (Courtesy of Adrian Bruce.)

Many fitting guides recommend a long settling period before assessing lens fit, particularly in the case of high-water-content lenses (e.g. 30 minutes); however, this is frequently impractical and unnecessary. Martin and Holden (1983), however, showed that high-water ionic lenses stabilize within a 10–15-minute period. Brennan et al. (1994) noted that the most effective time to predict the final fitting characteristics was approximately 5 minutes after lens insertion; however, they also noted that a proportion of patients show a relatively long settling time (>25 minutes) and hence the importance of reassessing lens fit at the first aftercare check.

Lens Fit Characteristics

Soft lenses rarely show the idealized fit described in textbooks and fitting guides (Young, 1996). Table 8.2 summarizes the factors affecting soft lens fit.

A summary of the characteristics of tight, loose and optimally fitting soft lenses can be seen in Table 8.3. It should be noted, however, that soft lenses rarely show all of the classic characteristics of a given type of lens fitting. Loose lenses, for instance, often show good centration despite excessive movement (Young, 1996).

OPTIMUM SOFT LENS FIT

The ideal soft lens will:

- be comfortable
- be perfectly centred, overlapping the limbus by at least 1 mm
- show approximately 0.3 mm of movement with a blink and a similar amount of lag on version gaze
- show easy movement on push-up followed by smooth re-centring
- have edges that align with the sclera without indenting the conjunctiva.

The minimum requirements of an acceptable-fitting soft lens are as follows:

- full corneal coverage at all times
- some movement on blink and / or version
- absence of excessive movement
- no conjunctival indentation or edge stand-off.

TIGHT SOFT LENS FIT

A typical tight soft lens fitting will:

- be initially comfortable but may ache or feel tired later in the wearing period

TABLE 8.2 Factors Affecting Soft Lens Fit

- Corneal geometry: corneal asphericity, curvature and diameter
- Contact lens geometry: back optic zone radius, peripheral thickness, central thickness
- Contact lens material: mechanical properties
- Post-lens tear film: non-invasive break-up time (NIBUT)
- Extraneous factors: pingueculae, lid tension

TABLE 8.3 Typical Soft Lens Fitting Characteristics

Criterion	Tight	Optimum	Loose
Comfort	Initially good, although eyes may feel tired later in wearing period	Good	Poor
Centration	Can be good or poor	Good	Possibly decentred
Post-blink movement	Little or none	0.2–0.4 mm	>0.4 mm
Lag on version or upgaze	Little or none	0.2–0.4 mm	>0.4 mm
Tightness on push-up	Difficult to dislodge and slow to recover	Easy to dislodge and smooth recovery	Very easy to dislodge and fast recovery
Peripheral fit	Conjunctival indentation	Aligned	Edge stand-off
Vision	Stable or possibly clearer after a blink	Stable	Variable

- display minimal or no movement with a blink
- be difficult to dislodge by the push-up test and will be slow to recover.

In extreme cases, there will be indentation of the scleral conjunctiva. The centration of the lens is not a helpful indicator of whether a lens is tight.

LOOSE SOFT LENS FIT

A typical loose-fitting soft lens will:

- be uncomfortable due to excessive lens movement or decentration
- sometimes show decentration and excessive movement on blinking (≥0.5 mm)
- be easily dislodged on push-up and fall quickly when the lower lid is retracted
- have an edge that may show some stand-off, especially at the inferior temporal edge.

Assessment of Fit

The visual assessment of soft lens fit should be undertaken with the aid of a slit lamp rather than a hand-held magnifier (e.g. Burton lamp). Only a slit lamp can give the magnification required to view the finer details of soft lens fit – for instance, the fit of the lens periphery.

COMFORT

The patient's reaction to the lens in terms of comfort is the first clue to the lens fit. A well-fitting soft lens is a comfortable lens. Tight-fitting lenses are also usually comfortable, but some discomfort or lens awareness may indicate a loose-fitting lens. One study found that 63% of loose-fitting lenses were graded as relatively uncomfortable (Young, 1996). Due to the overlapping distribution of corneal nerves, it is difficult for patients to locate precisely the source of any discomfort; however, it is worth asking the patient to describe the discomfort with questions such as:

- Can you feel the edge of the lens?
- Is the discomfort at the top or bottom edge of the lens?
- Is it more noticeable when you blink?
- Does the lens feel as if it is moving about in your eye?

Also, gauge the severity of any discomfort by observing the patient. Clearly, excessive lacrimation or blepharospasm would tend to suggest a more severe reaction.

It is wrong to think that new wearers require a prolonged adaptation period to the comfort of soft lenses in similar fashion to rigid lenses. Well-fitting soft lenses, once settled, should be virtually indiscernible to the patient.

CENTRATION

Some decentration is acceptable provided the lens shows corneal coverage at all times and does not appear to compromise comfort. Remember that the cornea extends beyond the HVID and that some overlap of the visible iris is necessary, ideally by about 1 mm.

As expected, loose-fitting lenses tend to show greater decentration. In one study, three-quarters of loose-fitting lenses showed decentration greater than 0.3 mm (Young, 1996). Tight lenses show similar centration characteristics to those of well-fitting lenses. In other words, tight lenses do not necessarily show perfect centration but can vary from perfect to noticeably decentred.

With most higher-power lens designs, the optic zone diameter will be reduced in order to minimize lens thickness. In these cases, it is important to ensure that any decentration does not compromise peripheral vision.

MOVEMENT

Some lens movement is necessary to maintain post-lens lubrication and, in turn, ensure a complete post-lens tear film. Excessive movement can cause unnecessary discomfort and disrupt vision. Post-blink movement is a more important indicator of tight rather than loose-fitting lenses as virtually all tight-fitting lenses show little or no movement (Young, 1996). Loose-fitting lenses do not necessarily show excessive movement and therefore the assessment of lens movement on its own is an inadequate measure of lens fit.

In a normal fit, the lens appears to remain stationary when the lid moves downward during the first part of the blink but then moves upwards by a small amount during the second part of the blink, returning to its original position immediately after the blink – hence the description 'post-blink movement'. Some loose fittings show a type of movement reminiscent of lid attachment with rigid lenses. The lens shows some downwards movement as soon as the lid starts to blink before showing the normal up-and-downwards movement. In some cases, the lens can be seen to move with the lid even during small changes in lid position.

Soft lens movement correlates surprisingly poorly with the pressure that the lens exerts on the eye, except where the lens exerts pressure above a certain threshold. In these cases, the lens tends to show no movement (Martin et al., 1989). In addition, Little and Bruce (1994) have shown that lens movement is affected by the state of the post-lens tear film. Depletion of the post-lens tear film due to lens dehydration may even result in lens adherence. In cases where patients present with lenses showing no movement, it is therefore wrong to assume that this is due to the lens geometry and other factors such as the patient's tear film and working environment should be considered.

Movement on sideways gaze (version lag) can be as sensitive an indicator of fit as post-blink movement. The assessment of upgaze lag is less useful and, in fact, a large proportion of well-fitting lenses show no movement on upgaze lag (Fig. 8.5).

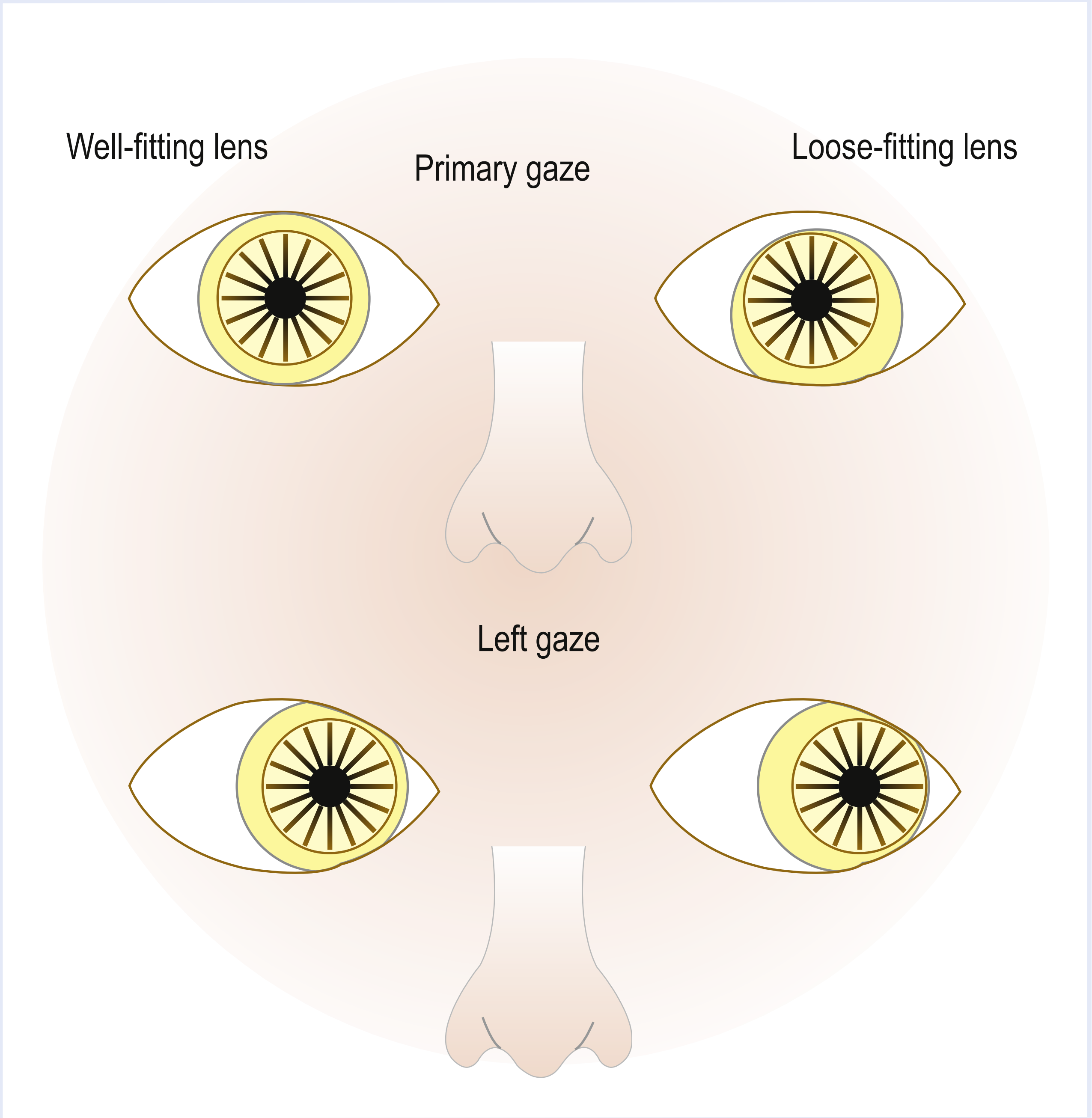

Fig. 8.5 Loose and well-fitting lenses in primary gaze and on version.

TIGHTNESS ON PUSH-UP

The assessment of lens fit using the push-up test is the most useful single test of lens fit (Fig. 8.6). This is undertaken by digitally moving the lens upwards, pushing the lower lid against the lens edge. The test consists of an assessment of the amount of force necessary to dislodge the lens upwards coupled with the speed of recentration of the lens from its dislodged position. As crude as it sounds, the push-up test has been shown to correlate closely with 'squeeze pressure', which is a measure of the mechanical properties of the lens and an index of the force exerted by the lens on a given eye (Martin et al., 1989). The test shows high predictive value and is equally sensitive for both tight and loose fits (Young, 1996).

If the lens is already decentred upwards it may be difficult to dislodge, thus giving a false impression of tightness. In this situation, lens fit can be checked by using the top lid to recentre the lens before performing the push-up test in the normal way. Lenses can also give the false impression of tightness because of post-lens dryness causing the lens to adhere to the eye. This is rarely seen during trial lens fitting but is occasionally seen in patients attending aftercare visits, particularly if the patient is prone to dry eye or has been in a dry atmosphere. In these cases, once the lens has been forcibly dislodged by push-up and the post-lens tear film is able to reform, the lens resumes its normal fitting appearance.

A variant of the test, the spring-back test, involves digitally displacing the lens sideways and observing the speed of recentration. However, this test is unnecessarily disruptive and not recommended.

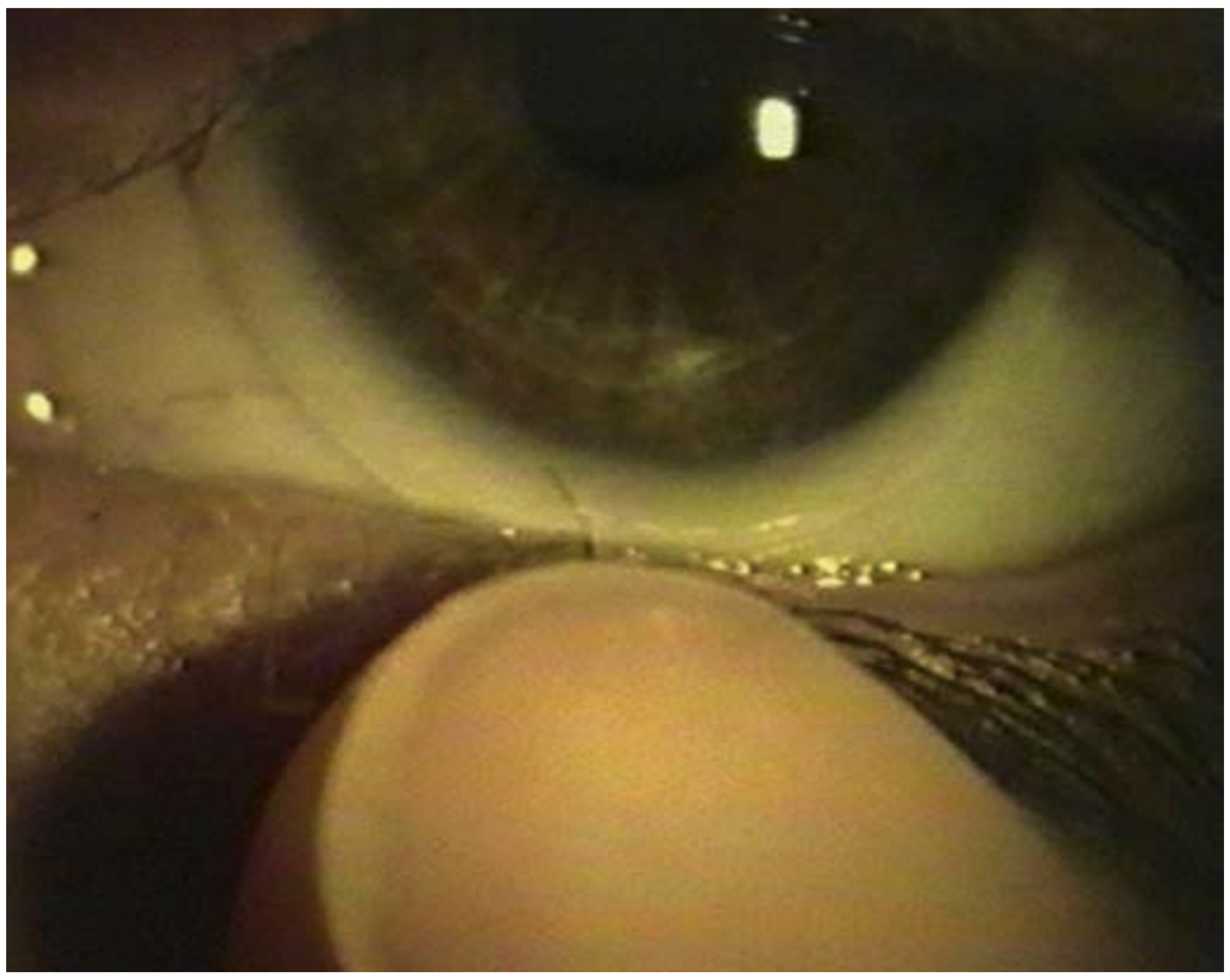

Fig. 8.6 Assessment of fit by the push-up test.

PERIPHERAL FIT

The peripheral fit is an important, but often overlooked, aspect of soft lens fit. A lens can show good centration and tightness on push-up but still show poor edge alignment. Even slight, barely visible edge stand-off can cause discomfort due to interaction with the lids (Fig. 8.7). Edge stand-off is often more easily disclosed by moving the lens closer to the limbus by push-up (Josephson, 1977).

The opposite case of excessive peripheral tightness is rarely seen with conventional hydrogel lenses owing to their relatively thin edges but is common with higher-modulus silicone hydrogel lenses. The type of constriction described in textbooks as vessel blanching is extremely rare and would occur only with a thick lens that was tightly fitting in every respect. Particularly with silicone hydrogel lenses, it is useful to examine the periphery under magnification for signs of indentation of the bulbar conjunctiva. When present, this may also be visible on lens removal through pooling of fluorescein in the indentation.

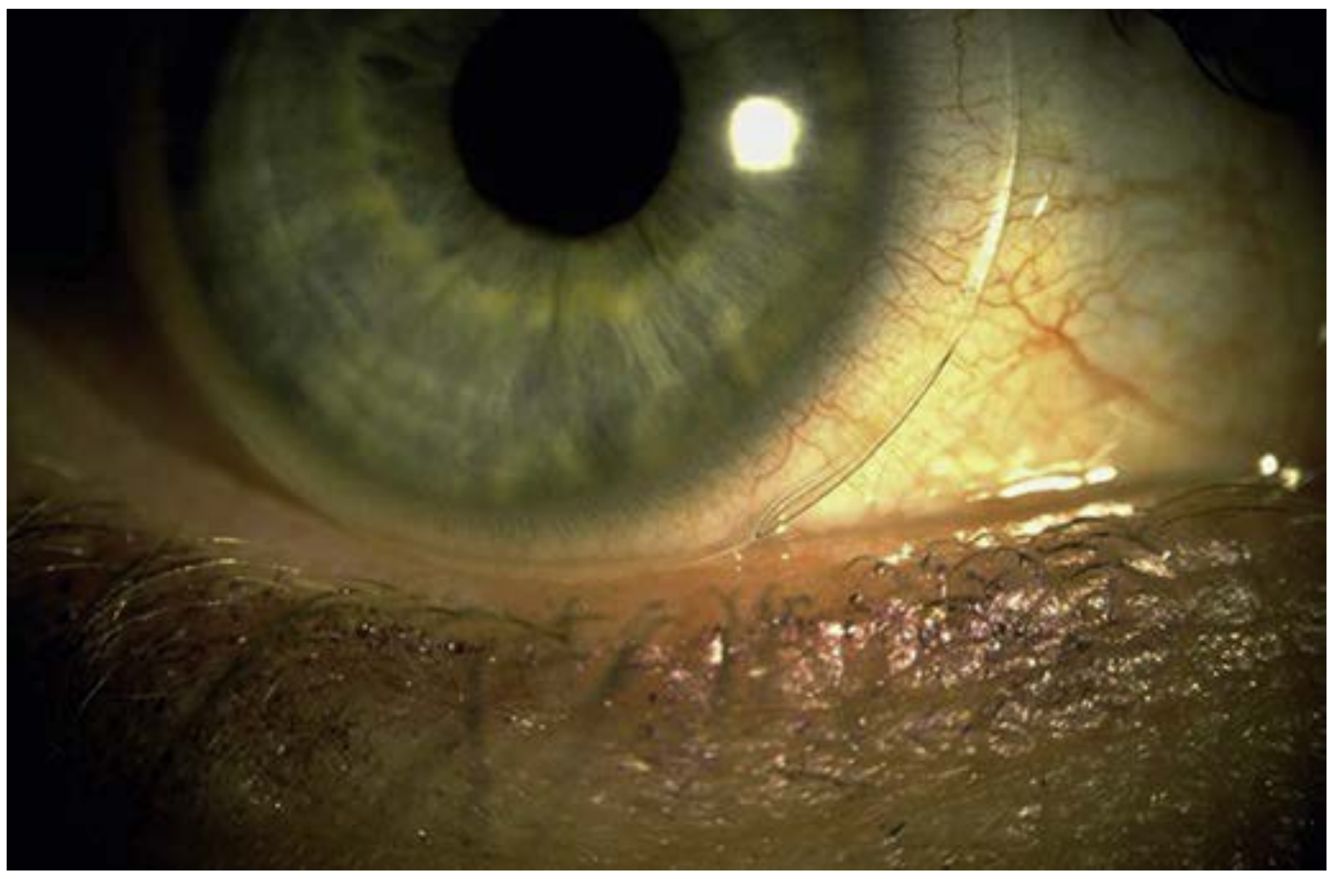

Fig. 8.7 Gross edge stand-off; even slight edge stand-off can cause discomfort.

Even if the lens periphery is not tight, close examination can be useful in identifying relatively thick edges that might cause discomfort through interaction with the lid wiper, particularly at the 2 and 10 o'clock positions.

VISION

An overrefraction is usually unnecessary as part of the fitting procedure. Spherical soft lenses, because of their thinness and flexibility, rarely support a tear lens between the lens and cornea. In the case of with-the-rule astigmatism, the required contact lens power usually corresponds to the vertex distance-corrected spectacle sphere (assuming minus cylinder); thus no adjustment is necessary for cylinder power. On the other hand, with against-the-rule astigmatism, the required power will incorporate approximately half of the cylinder power. Where an overrefraction yields an unexpected result, this can usually be explained by checking the lens power with a focimeter (see Chapter 7).

Unstable vision may indicate a loose, relatively mobile fit. In rare cases, unstable vision that clears with a blink indicates a steep central fit. However, this is more common with relatively thick or high-modulus lens designs, but even then is rarely seen.

OTHER METHODS OF FIT ASSESSMENT

Other techniques for assessing lens fit have been suggested; however, the basic methods described above are usually sufficient. Other methods include the following:

- Assessing keratometry mires – the keratometry mires tend to distort when the lens is not aligned with the lens surface. Mire distortion tends to clear immediately after a blink with tight-fitting lenses and between blinks with loose-fitting lenses.
- Videokeratoscopy – this gives a more detailed picture than keratometry. The final contour map, however, unlike keratometry is a static assessment.
- Retinoscopy – this can be useful in confirming that the optic zone gives proper coverage of the pupil, which may be particularly useful with some bifocal designs.

Soft Lens Fitting Problems

DISCOMFORT

Two aspects of the lens design can affect comfort: total diameter and edge design. However, other possibilities should be ruled out first, such as:

- foreign body
- lens inside out
- lens damage
- lens spoilation.

As there is a relatively wide transition zone between the cornea and sclera, a soft lens may appear to just cover the cornea when in reality the lens edge is irritating the peripheral cornea. If the lens decentres so that the edge is close to the limbus, the patient is usually able to localize the discomfort to that part of the limbus.

Many larger corneas show marginal corneal coverage with standard-diameter soft lenses. Since most soft lens brands are offered in one diameter only, the obvious remedy is not available and it is necessary to try a different lens type. However, as lenses with a steeper BC have a slightly larger surface area than do their equivalent flatter versions, changing BC can sometimes overcome the problem. As a rule of thumb, steepening BC by 0.4 mm will result in an increase in diameter of 0.2 mm on the eye.

Relatively large changes in peripheral thickness can be made to a lens design without affecting comfort (Young et al., 1993). Nevertheless, some thinner-edged designs do appear to give better comfort than others. As with rigid lenses, there does appear to be an adaptation effect. However, as comfort appears to be the characteristic that patients most value, the best approach is to find a design that is immediately comfortable for a particular patient. As noted earlier, some cases of edge sensation may be related to the peripheral fit.

In case of dryness-related discomfort, an alternative approach is to change to a more wettable material and / or dehydration-resistant material, such as omafilcon A or senofilcon A (Lemp et al., 1999; Riley et al., 2006).

INAPPROPRIATE DIAMETER

Too Large

Greater than usual coverage of the sclera is not in itself a clinical problem. However, the fact that the lens is required to flex close to the optic zone junction in order to align with the limbus and sclera can result in areas of increased mechanical pressure. When concentrated at the edge, this can result in conjunctival indentation. When too large a diameter results in poor flexure in the midperiphery, this can lead to superior arcuate staining (Young and Mirejovsky, 1993).

Another problem with large lenses is that the lens may be visible on the eye, particularly if the lens has a thick periphery or incorporates a deep handling tint.

Unfortunately, there are few soft lenses available in diameters smaller than 14.0 mm. Also, as noted earlier, comparing the labelled diameters of soft lenses is not necessarily a reliable guide to their on-eye performance. It is therefore necessary for practitioners to gain an appreciation of which lenses are relatively small on-eye; current examples are Air Optix Night & Day (Alcon) and Soflens 59 (Bausch & Lomb).

Too Small

Lenses that are too small can cause peripheral corneal staining as well as discomfort. Again, it is necessary to have an appreciation of which lenses are relatively large once equilibrated on the eye; current examples of relatively large lenses are Proclear (CooperVision) Air Optix Aqua (Alcon) and Acuvue Oasys 1·Day (Johnson & Johnson).

INAPPROPRIATE FIT

Too Loose

Loose-fitting lenses can also cause peripheral corneal staining and symptoms of discomfort and variable vision. Patients may also complain of lenses being displaced from the cornea during wear.

The first possibility to consider is whether the lens is inside out. Switching to a similar lens of steeper BC may not always overcome the problem, particularly with thin lens designs. It may be necessary therefore to change to a lens with a tendency towards tight fitting.

Too Tight

Tight lenses induce greater levels of staining than do well-fitting lenses and the prevalence of staining increases with increasing degree of tightness. Tight-fitting lenses tend to be comfortable but patients occasionally complain of aching eyes later in the wearing period.

POOR VISUAL ACUITY

Occasionally, soft lenses fail to give acceptable vision even when the optimum power appears to have been selected.

Possible reasons for poor vision include the following:

- uncorrected astigmatism
- lens deposits
- poor surface wetting
- lens imperfections.

Slit-lamp inspection of the lens on the eye will indicate whether the problem is poor surface wetting as a result of spoilation or merely poor tear quality is to blame. Generally, if these are severe enough to affect vision, they will be easily visible on slit-lamp examination.

As with spectacle lenses, contact lenses very occasionally show optical imperfections that, in turn, affect vision. These include waves, distorted optics and multiple zones of power. The focimeter image may give an indication, but the lens optics can also be inspected by dabbing the lens dry with a tissue wipe and viewing through the lens with the naked eye while holding it towards a light source.

In the event of no obvious cause, the best remedy is to replace the lens to see whether this overcomes the problem.

VARIABLE VISION

When the visual acuity is normal but the patient complains of variable vision, the following causes may be suspected:

- incorrect back vertex power, e.g. over-minus, under-plus
- poor binocular balance
- excessive lens movement, i.e. loose fit
- poor pre-lens tear film.

Fitting Caucasian versus Oriental eyes

Differences in ocular anatomy between Caucasian and Oriental eyes can potentially impact soft contact lens fitting. In a UK-resident Chinese population, Lam and Loran (1991) observed that corneas of UK-resident Chinese people were steeper and smaller than Caucasian eyes. However, Hickson-Curran et al. (2014) noted that Chinese and Japanese corneas tended to be slightly flatter but to show similar asphericity in the flatter meridian than did Caucasian. Also, Oriental eyes tend to show a narrower palpebral aperture: on average, about 1.0 mm smaller than Caucasian eyes (Lam and Loran, 1991; Hickson-Curran et al., 2014). A comparison of Caucasian and British Asian eyes noted smaller corneas in the British Asian population but no difference in curvature or asphericity (Hall et al., 2013).

Hickson-Curran et al. (2016) evaluated the effect of ocular topography on soft contact lens fit 547 subjects from two ethnic groups – Caucasian ($n=250$) and Chinese ($n=297$). Subjects were fitted with a 1-Day ACUVUE spherical lens in two base curves – 8.50 and 9.00 mm. They observed that the steeper base curve (8.50 mm) spherical lenses gave an acceptable overall lens fit with 98% or more of subjects in both groups, while the flatter lens (9.00 mm) was acceptable in a significantly higher proportion of the Chinese compared with the Caucasian group (96 versus 82%, $p<0.0001$). The main difference in fit between groups was for centration; there was significantly less decentration with the Chinese group (8.50 base curve: 39 versus 72%, $p<0.0001$; 9.0 base curve: 63 versus 85%, $p=0.02$). The 8.5 mm base curve showed good centration for 97% of Caucasian eyes and 96% of Chinese eyes. Overall, they concluded that the lens tested in this study fitted a large proportion of both Chinese and Caucasian eyes and is robust to the differences in ocular dimensions between the two ethnic groups examined.

Conclusion

As has been seen from reading this chapter, the fitting of soft contact lenses is not a simple formulaic task. Careful thought needs to be given to selecting a lens of appropriate material, dimensions and wearing modality to match the ocular characteristics and lifestyle preferences of the individual patient. Using a wide range of lens brands gives greater flexibility and increases the chance of arriving at the best solution expeditiously.

Access the complete references list online at http://www.expertconsult.com.

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9

Soft Toric Lens Design and Fitting

RICHARD G LINDSAY

Introduction

The use of soft toric lenses (in preference to spherical soft lenses) is indicated when there is ocular astigmatism present, be it corneal or non-corneal, that warrants correction. Unlike rigid lenses, soft lenses do not mask corneal astigmatism but rather conform to the shape of the cornea. Consequently, correcting ocular astigmatism with soft lenses requires that cylinder be incorporated into the back vertex power (BVP) of the lens.

Numerous manufacturers of soft contact lenses have made extremely optimistic claims of their spherical lenses being able to correct satisfactorily astigmatism of between 1.00 and 2.00 D. Only rarely is this achieved. Bernstein et al. (1991) showed that there was no statistically significant masking of corneal cylinder with standard-thickness soft spherical lenses. Indeed, the most helpful indication of the likely residual astigmatism found while wearing a spherical soft contact lens is the ocular astigmatism determined from an accurate subjective spectacle refraction.

For many years it was held that prospective contact lens wearers with clinically significant astigmatism could not be successfully fitted with soft lenses. Since the early 1980s, however, notable advances in soft toric lens technology have been made such that the correction of astigmatism with soft lenses is now a viable option for the majority of these patients. Indeed, annual contact lens fitting surveys over the last 10 years have consistently demonstrated a commensurate increase in toric lens fitting as a proportion of all soft lenses fitted. This is evident from Fig. 9.1, which shows the extent of toric soft lens fitting as a percentage of all soft spherical and toric lenses prescribed in seven nations between 2000 and 2015 (Morgan et al., 2016).

Based on the distribution of astigmatism in prospective contact lens wearers, Holden (1975) determined that, if all astigmatism of 0.75 D or more were corrected, 45% of lens wearers would need toric lenses. This threshold is shown as a dotted line in Fig. 9.1. It is evident from Fig. 9.1 that soft toric lens fitting has evolved to the point where nearly all those with clinically significant astigmatism are being corrected with toric lenses.

Criteria for Use of Soft Toric Lenses

When deciding whether or not to prescribe a soft toric lens, practitioners should avoid using criteria such as 'all patients with cylinders greater than a certain amount should be fitted with soft toric lenses.' Instead, each patient should be assessed separately, taking into account the following factors.

DEGREE OF ASTIGMATISM

As a generalization, 1.00 D or more of astigmatism should be corrected, although there will be significant variability between patients. Holden (1975), in discussing the criteria for the prescribing of toric lenses, showed that 45% of the population required a cylindrical correction of up to 0.75 D and 25% of the population required a correction of 1.00 D or more. A more recent study by Young et al. (2011) revealed that the prevalence of patients showing astigmatism of 0.75 and 1.00 D or greater in at least one eye was 47% and 32%, respectively. As mentioned previously, the current soft toric lens prescribing rate suggests that almost all cases of astigmatism 0.75D D or more are now being fitted with soft toric lenses.

CYLINDER AXIS

The axis of the ocular cylinder is also an important factor. For example, an uncorrected cylinder with an oblique axis will cause greater degradation of visual image compared with an equivalent amount of uncorrected with-the-rule or against-the-rule astigmatism (Lindsay, 1998).

OCULAR DOMINANCE

Uncorrected astigmatism is far more likely to be accepted by the patient if it is in the non-dominant eye. For example, patients may tolerate uncorrected cylinder of up to 2.00 D in their non-dominant eye, while at the same time requiring that cylinder as small as 0.50 D be corrected in their dominant eye. Related to this is the situation where a patient has unequal visual acuities. In this case, higher degrees of uncorrected astigmatism will usually be tolerated in the eye with the poorer acuity.

VIABILITY OF OTHER ALTERNATIVES

The practitioner also needs to consider whether soft toric lenses are the best option or whether the patient would be better off with spectacles or rigid lenses. For example, a patient with high degrees (>5.00 D) of both corneal and spectacle astigmatism would most likely achieve better acuities with a rigid toric lens.

VISUAL NEEDS OF THE PATIENT

Usually, the less critical the visual task the greater is the amount of astigmatism that can be left uncorrected (and vice versa). For example, a musician may require that a cylinder as small as 0.50D be corrected to enable music to be read. In contrast, a person with no specific critical visual tasks may be happy with a cylinder as high as 2.00 D left uncorrected so long as the spherical component of the refractive error is corrected.

Design of Soft Toric Lenses

Satisfactory visual performance with soft toric lenses is dependent upon two key design components – surface optics and lens stabilization.

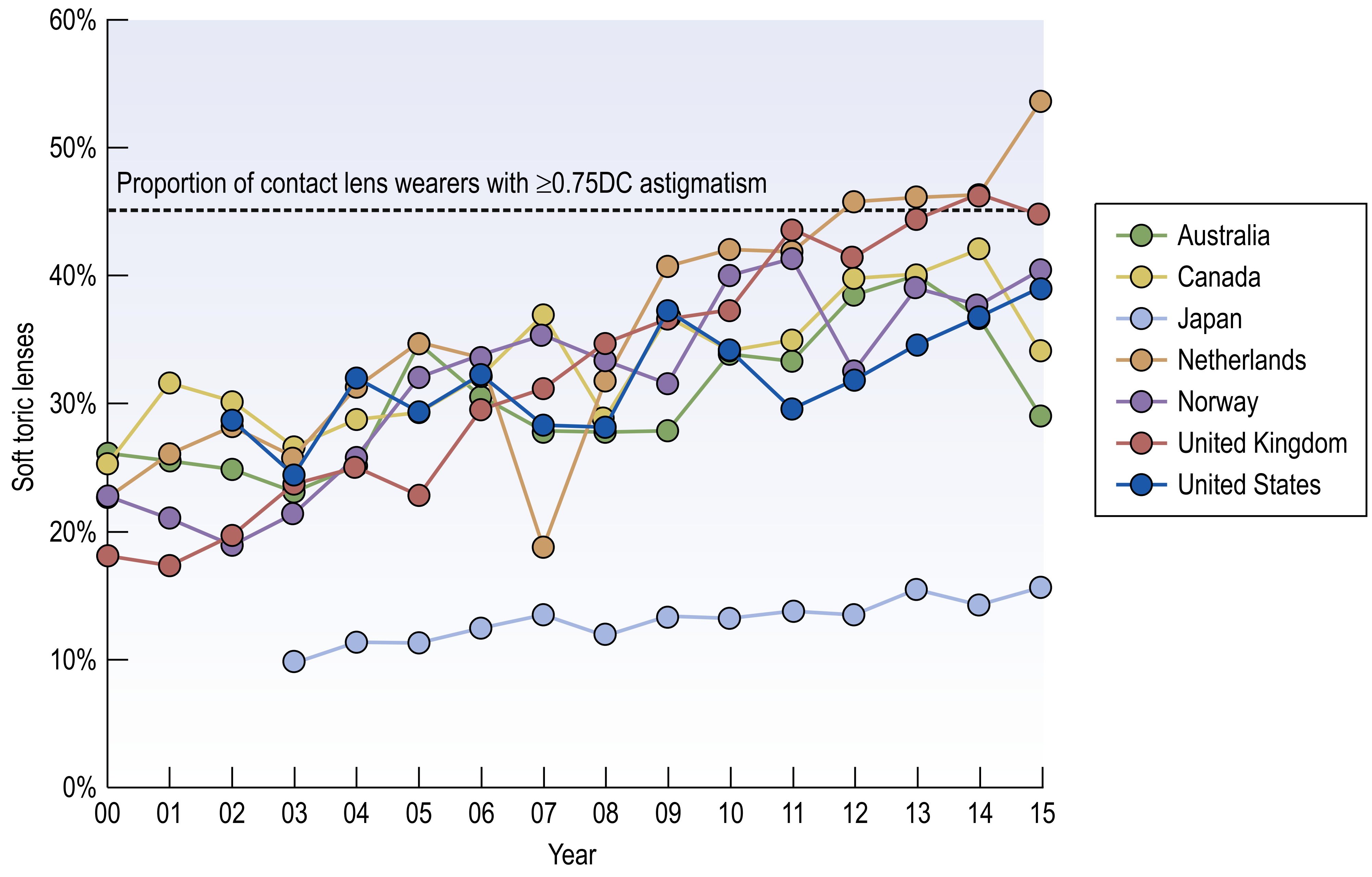

Fig. 9.1 Extent of toric soft contact lens fitting as a percentage of all soft spherical and toric lenses prescribed in seven nations between 2000 and 2015.

SURFACE OPTICS

The two principal categories of surface optics are as follows:

1. Toroidal back surface with a spherical front surface
2. Spherical back surface with toroidal front surface.

With soft toric lenses, regardless of which of the above optical configurations is prescribed, the end result on the eye will be a bitoric lens form owing to the wrapping of the front and back surface of the lens onto the cornea.

The optical considerations for soft toric lenses are different from those encountered when using rigid lenses. This is primarily because a soft toric lens will tend to wrap onto the cornea such that a negligible tear lens forms between the back surface of the lens and the front surface of the cornea. Consequently, the optical principles of rigid toric lenses do not apply. There are no tear lens calculations to perform and all the ocular astigmatism will usually be corrected by incorporation of cylinder into the BVP of the soft toric lens.

The choice of design (i.e. toric back surface versus toric front surface) is generally based more on considerations relating to manufacture, lens stability and physiological performance. Currently, the majority of soft toric lenses prescribed globally are of a planned-replacement form and virtually all of these lenses are mass-produced by a process of cast moulding. All other soft toric lenses are custom made for the patient by a process of either crimping or generating, the latter being a specific form of lathe cutting devoted to the production of toric surfaces. As a general rule, generated toric lenses will be thinner and show better reproducibility than do those made from crimping techniques.

STABILIZATION TECHNIQUES

All forms of soft toric lenses need to be stabilized so that the toric optics of the lens can be maintained in the desired orientation in order to correct the ocular astigmatism. The aim is to minimize rotation from the ideal in-eye orientation. The orientation of a soft toric lens on the eye must be predictable and consistent, otherwise suboptimal vision will result. The development of the technique of dynamic stabilization in the 1980s has resulted in an overall improvement in the performance of soft toric lenses.

Toroidal Back Surface

Some practitioners and laboratories believe that a soft toric lens with a toric back surface will generally locate better than a front surface toric lens, because it is believed that the back toric surface is more likely to align with, or 'lock onto', the matching toroidal corneal surface. However, experience has shown that a toroidal back surface alone is insufficient to achieve lens stabilization.

Prism Ballast

The theory of prism ballast is that base-down prism is incorporated into the lens so that the lens will be heavier at the prism base (due to excess lens mass). Gravity then acts to cause the prism base to locate inferiorly.

Prism ballast has long been used as a technique for stabilizing toric forms of lenses, but it does have certain disadvantages when applied to soft lens designs. The additional thickness brought about by the use of a prism can be a problem in that it reduces oxygen transmissibility in the thick prism zone and can also cause physical discomfort in patients with sensitive lids. In addition, soft toric lenses incorporating prism ballast often show excessive downward mislocation on the eye. The thicker edge in the region of the prism base can be thinned during the manufacturing stage to form a 'comfort' chamfer (Edwards, 1999), although this will slightly negate the intended thickness differential along the vertical axis of the lens. The problem here is finding an acceptable compromise between comfort and lens stability.

One of the difficulties that arises with the use of prism ballast is that, if it is going to be prescribed monocularly, it may cause vertical prismatic effects that can make the patient uncomfortable. This then requires the use of a similar prism for the other eye, which can prove difficult if the other eye requires a spherical lens or is emmetropic. Fortunately, however, prism ballast does not often give rise to binocular problems (Gasson, 1977).

This design feature is perhaps considered inferior to dynamic stabilization (see below) for maintaining the orientation of a soft toric lens on the eye; nevertheless, prism ballast is the method of stabilization that is used predominantly in disposable toric lens designs, which have proved to be reasonably successful in clinical practice.

Peri-ballast

This method of lens stabilization features a lens with a minus carrier (peripheral zone), with the carrier being thicker inferiorly. In other words, the prismatic thickness profile changes are confined to the lens carrier, where the carrier is thicker inferiorly (prism base-down). This design is fabricated simply by removing the high-minus lenticular carrier from the superior portion of the lens. In effect, it is similar to prism ballast except that with peri-ballast all the prism is outside the region of the optic zone.

Truncation

Truncation refers to the technique of slicing off the bottom of the lens so as to form a 'shelf' that will rest upon – and therefore align with – the lower lid. This is a reasonably successful method of stabilizing lenses with thick edges, especially when combined with prism ballast (Fig. 9.2). Either a single lower truncation or a double truncation (where both the top and bottom of the lens are sliced off) can be used (Strachan, 1975). With the former, the truncated section of the lens that is removed can be anywhere between a sag of 0.5 and one of 1.5 mm.

There are problems with the use of truncation in soft toric lens fitting. The truncated edge can make the soft lens uncomfortable to wear. The measurement of the lid angle can be difficult and imprecise. Quite often the truncation does not work, with the lid angle appearing to have no effect on the positioning or location of the truncated lens. Another difficulty with truncations (and prism ballasting) is the instability that can occur with oblique cylinders. The uneven thickness produced by oblique cylinders can make lens stabilization very difficult. For these reasons, soft toric lens truncation is rarely used today.

Dynamic Stabilization

The technique of dynamic stabilization was initially developed by Fanti (1975) and this is currently the most commonly used method of stabilization for soft toric lenses. With this technique, the dominant lens orientation effect is achieved by pressure from the upper lid (primarily) and the lower lid. Hanks (1983) used the analogy of the 'watermelon seed' to illustrate how dynamic stabilization works. Simply put, pressure applied to the thin end of a watermelon seed by the fingers (i.e. the pressure exerted on a thin zone of a lens between the upper lid and globe) causes the watermelon seed to move away from the fingers (i.e. causes the lens to orient away from the squeezing force of the eyelid and globe). Hanks (1983) demonstrated that the effect of gravity is insignificant, and that the effect of the thickness profile interaction with the upper lid as described above is the dominant stabilizing component.

With dynamic stabilization, the contact lens toricity is confined to the central portion of the lens. The superior and inferior ('dynamic stabilization') zones of the lens incorporate a thickness differential. The action of the lids on these superior and inferior lens chamfers serves to stabilize the lens in the correct orientation. Such a design is shown in Fig. 9.3. Many similar approaches, referred to as 'double slab-off', 'thin-zone' or 'reverse prism' designs, are manufactured throughout the world.

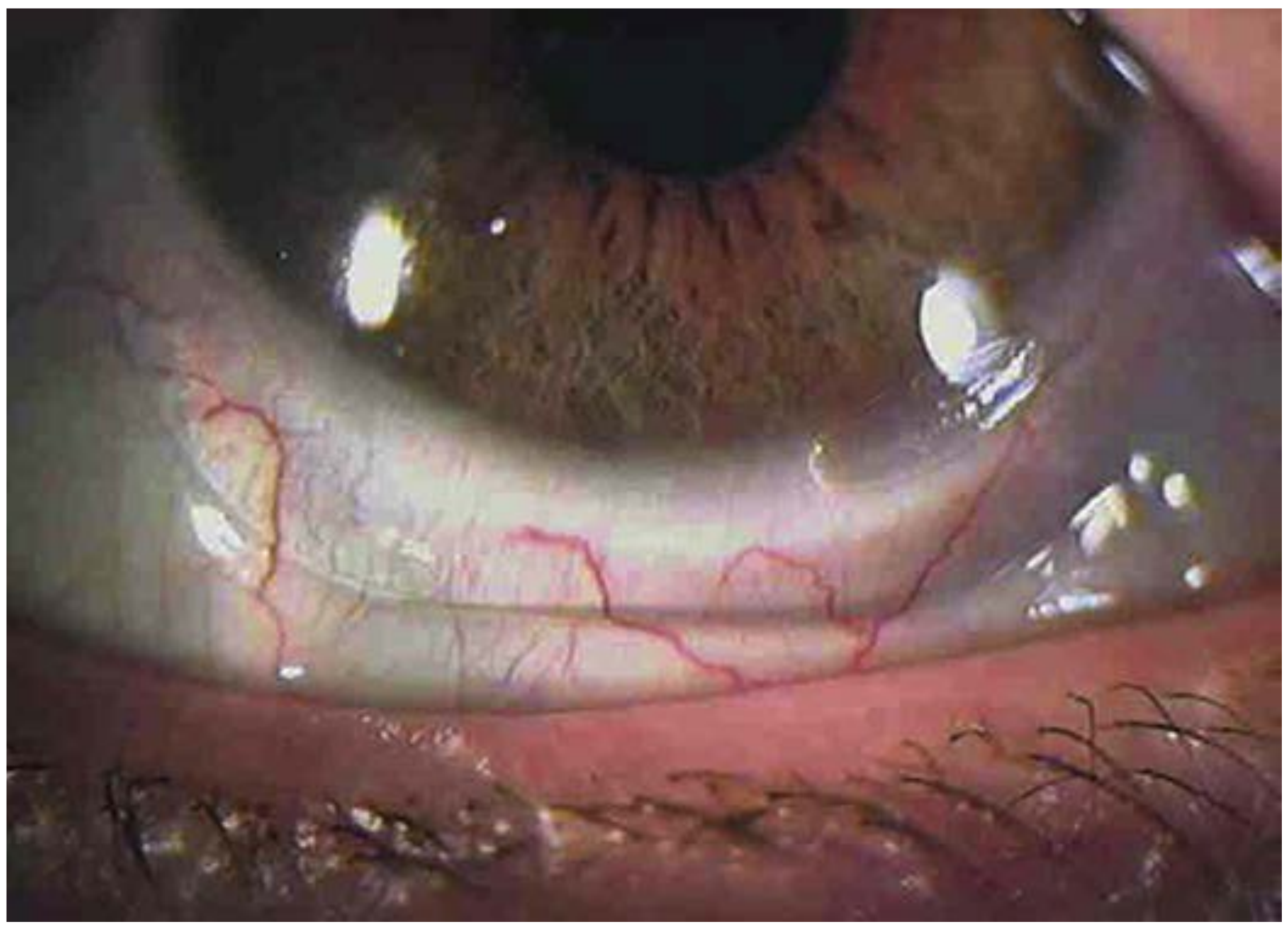

Fig. 9.2 A prism-ballasted soft toric lens with a single (inferior) truncation. The truncation has been cut at the angle of the middle third of the lower lid, but in this photograph the patient had to look up in order to bring the truncation near the lower lid. The lid margin may thus only have a limited effect on the truncation in this patient. Note the prominent bubble under the lens near the truncation – a common problem with these lenses. (Adapted from Tan, J., Papas, E., Carnt, N. et al. (2007). Performance standards for toric soft contact lenses. Optom. Vis. Sci., 84, 422–428.)

Dynamic stabilization avoids the complications of truncation and prism ballast. Oxygen transmissibility is not reduced as additional thickness is generally not incorporated into the lens. Indeed, the excessive thickness of prism ballast lenses can be avoided and, by producing toroidal back surfaces, the average lens thickness is only slightly greater than that of equivalent spherical designs. The main disadvantage of this design is that the thickness differential that can be achieved at the edge of the lens is dependent on the spherical power of the lens. Lower-powered lenses will have a reduced thickness differential and, for this reason, a design incorporating prism ballast is often more effective in stabilizing a soft toric lens that has a low spherical power component (Snyder, 1998).

The orientation in which a lens incorporating dynamic stabilization is inserted into the eye is generally not important since the action of the lids during blinking will quickly stabilize the lens in the correct orientation. With some designs, a larger, thinned zone is provided superiorly to utilize the fact that most of the blink action is performed by the upper eyelid. With these designs it is more important that the lens is inserted the correct way up. To facilitate this – and to assist the practitioner in determining the degree of in-eye lens rotation – such lenses will generally have some form of marking at the 6 or 12 o'clock position.

Principles of Correction

It is clear that to produce a stable ocular correction for the astigmatic eye the lens must align closely over the central cornea in front of the pupil. It must provide the correct power while it is in situ and must stabilize effectively to prevent the rotation of the meridional powers away from their intended orientation.

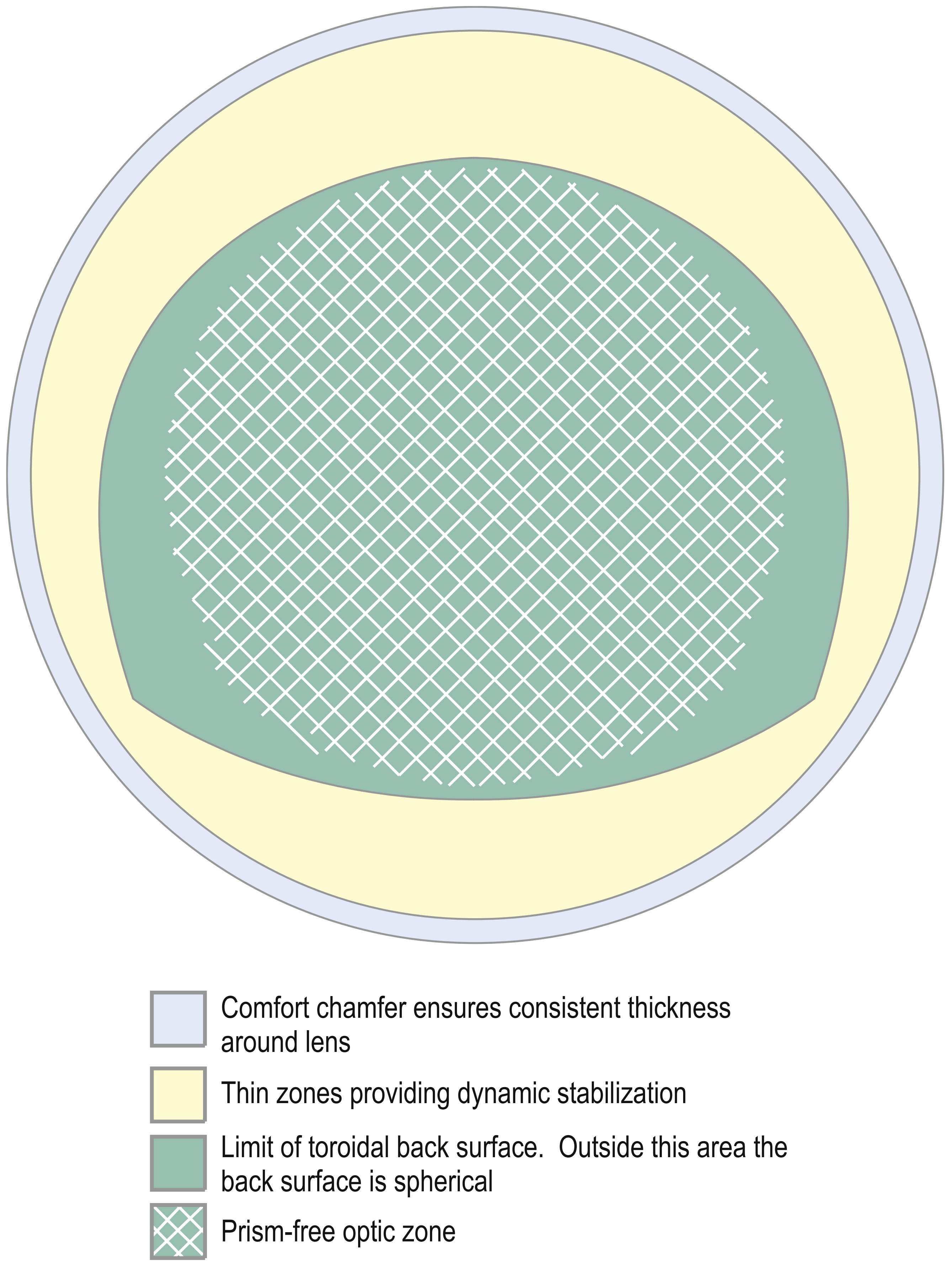
Comfort chamfer ensures consistent thickness around lens
Thin zones providing dynamic stabilization
Limit of toroidal back surface. Outside this area the back surface is spherical
Prism-free optic zone

Fig. 9.3 Design features of a soft toric lens that help to minimize lens rotation. Note the prism-free optic zone in the toroidal region of the lens.

FITTING

The fitting principles for soft toric lenses are very similar to those for soft spherical lenses, as outlined in Chapter 8. A well-fitting lens is comfortable in all directions of gaze, gives complete corneal coverage and appears properly centred. On blinking there should be about 0.25–0.5 mm of vertical movement when the eye is in the primary position. On upwards gaze or lateral movements of the eye, the lens should lag by no more than 0.5 mm.

The total diameter of the lens is very important because this parameter will influence both lens centration and lens stability. Generally, when specifying the lens diameter the practitioner should err on the large side, as a larger diameter means that more area is available for the stabilization zones to take effect in the periphery of the lens.

Some practitioners advocate fitting soft toric lenses that are very steep (tight) with minimal lens movement, on the assumption that this will aid stability and reduce lens rotation. With the designs available today, however, this is not necessary. If a lens is too tightly adherent to the eye, it will not be affected by the locating forces designed to stabilize lens orientation (Holden, 1976). Consequently, a steeply fitting lens may decrease stability and lead to undesirable factors such as limbal indentation and fluctuating vision – the latter being caused by the soft lens vaulting the corneal apex.

A well-fitting lens will reveal stable lens orientation with a quick return to axis if mislocated. A tight-fitting lens will show stable lens orientation but a slow return to axis if mislocated. A loose-fitting lens will demonstrate an unstable and inconsistent lens orientation (Hanks and Weisbarth, 1983).

BACK VERTEX POWER DETERMINATION

The determination of BVP for a soft toric lens is much easier than that for a rigid toric lens. Due to the absence of a tear lens, the BVP for a soft toric lens should be similar to the spectacle refraction (or ocular refraction if the vertex distance effect is significant).

The BVP of the lens can be determined either empirically or by performing a spherocylindrical overrefraction (SCO) over a diagnostic lens. With empirical prescribing, the BVP ordered for the soft toric lens will be equal to the ocular refraction of the patient, based on the assumption of an afocal tear layer under the soft toric lens. For the latter method, an SCO may be performed over either a spherical or a toric trial lens. Use of a spherical trial lens is generally preferred, as an SCO with a toric trial lens may require complex calculations involving oblique cylinders in order to determine the required lens power. When using a spherical trial lens, the resultant toric lens power is simply calculated by adding the SCO to the BVP of the trial lens. With both methods, some arbitrary allowance for lens rotation may have to be incorporated into the final lens prescription.

EFFECT OF LENS ROTATION

A considerable degree of cylindrical error can be induced when a lens does not stabilize satisfactorily and rotates away from the intended orientation (Lindsay et al., 1997); this phenomenon is demonstrated in Appendix I. For example, if the contact lens correction incorporates a power of plano/−2.00 DC × 180, Appendix I reveals that a mislocation of the axis by 10° results in a spherocylindrical error of +0.35/−0.69 DC ×40. A useful rule of thumb here is that a lens made to specification but mislocating on the eye will produce an overrefraction with a spherical equivalent equal to zero. Where the sphere or cylinder power is incorrect, the spherical equivalent of the refraction will not equal zero (Long, 1991).

PREDICTING LENS ROTATION

Hanks and Weisbarth (1983) showed that, on average, soft toric lenses will tend to rotate nasally by about 5–10°, where nasal rotation is designated as rotation of the inferior aspect of the lens towards the nose. They also showed, however, that there was significant variability between soft toric lens wearers in the actual amount and direction of lens rotation; variations also occur between different lens designs.

The nature of both contact lens materials and their associated designs is continually changing; performance characteristics that were typical for toric soft contact lenses of a decade ago may be of questionable relevance today. Tan et al. (2007) have examined the performance of several lenses with differing methods of stabilization and have developed recommended performance standards for toric soft contact lenses (Table 9.1).

The variability in performance of soft toric lenses can be due to the following factors.

Lid Anatomy

Variation in lid tension (tightness), lid location, lid angle, lid symmetry and palpebral aperture size can all have a significant effect on the location and stability of a toric lens on the eye. Tight lids are more likely than loose lids to affect lens movement and location (Lindsay, 1998) and it has been shown that

TABLE 9.1 Recommended Performance Standards

	Excellent	Acceptable	Poor
Comfort (1–100)	≥90	80–89	<80
Mean lens mislocation	≤±6°	±7° to ±10°	>10°
SD of lens location	<±6°	± 6° to ±10°	>±10°
Rotational recovery/10 blinks	>10°	6–10°	<6°
% Lenses within ±10°	≥90	70–89	<70

(Reproduced from Tan, J., Papas, E., Carnt, N. et al. (2007). Performance standards for toric soft contact lenses. Optom. Vis. Sci., 84, 422–428.)

– for prism-stabilized lenses – a smaller palpebral aperture size is associated with a more stable lens orientation (Young et al., 2002).

Lens–Eye Relationship

The optimal fitting relationship between the lens and the eye may vary from one patient to the next. The type of fit (steep, alignment or flat) will, in turn, have a significant bearing on lens position. For example, the degree of adherence between lens and eye is a very important factor (Holden, 1976). If a lens is too tightly adherent to the eye it will not be affected by the locating forces designed to stabilize lens orientation. Conversely, Young et al. (2002) have shown that less lens movement is associated with more stable lens orientation; however, increased tightness is associated with slower reorientation speed.

Lens Thickness Profile

It has been noted previously that with dynamic stabilization the thickness profile interaction with the upper lid is the dominant stabilizing component. Although most soft toric lenses manufactured today have the contact lens toricity confined to the central portion of the lens, a thickness differential due to the astigmatic correction can still have a significant effect on lens location.

The lens thickness profile is determined by the power of the lens, in particular the axis and magnitude of the astigmatic correction. For soft toric lenses incorporating dynamic stabilization, Gundel (1989) showed that rotational influence is greatest for lenses with cylinders at oblique axes (either 30–60° or 120–150°), followed by lenses incorporating correction for with-the-rule astigmatism (150–30°), and is least for lenses with against-the-rule axes (60–120°).

Gundel (1989) postulated that the principal factor affecting lens rotation is the initial point of contact between the upper lid and the thicker meridian of the lens. For toric lenses with oblique axes, the implication is that there will be notable rotational effects as contact from the upper lid will always affect one edge of the thicker meridian before the other. As the upper lid comes down, it will force the lens down at this first point of contact, causing it to rotate in a certain direction. This principle is illustrated by the example shown in Fig. 9.4. A mislocating effect also occurs with lenses correcting for with-the-rule astigmatism as the lid contraction angle will usually be at a slight angle to the thickest axis of the lens (Holden, 1975). For toric lenses incorporating a correction for against-the-rule astigmatism, upper-lid contact with the thicker (horizontal) meridian will be fairly symmetrical and so the rotational effect is minimal. However, the influence of the lower lid can override that of the upper lid depending on its position, tightness and amount of lateral movement (Young, 2003).

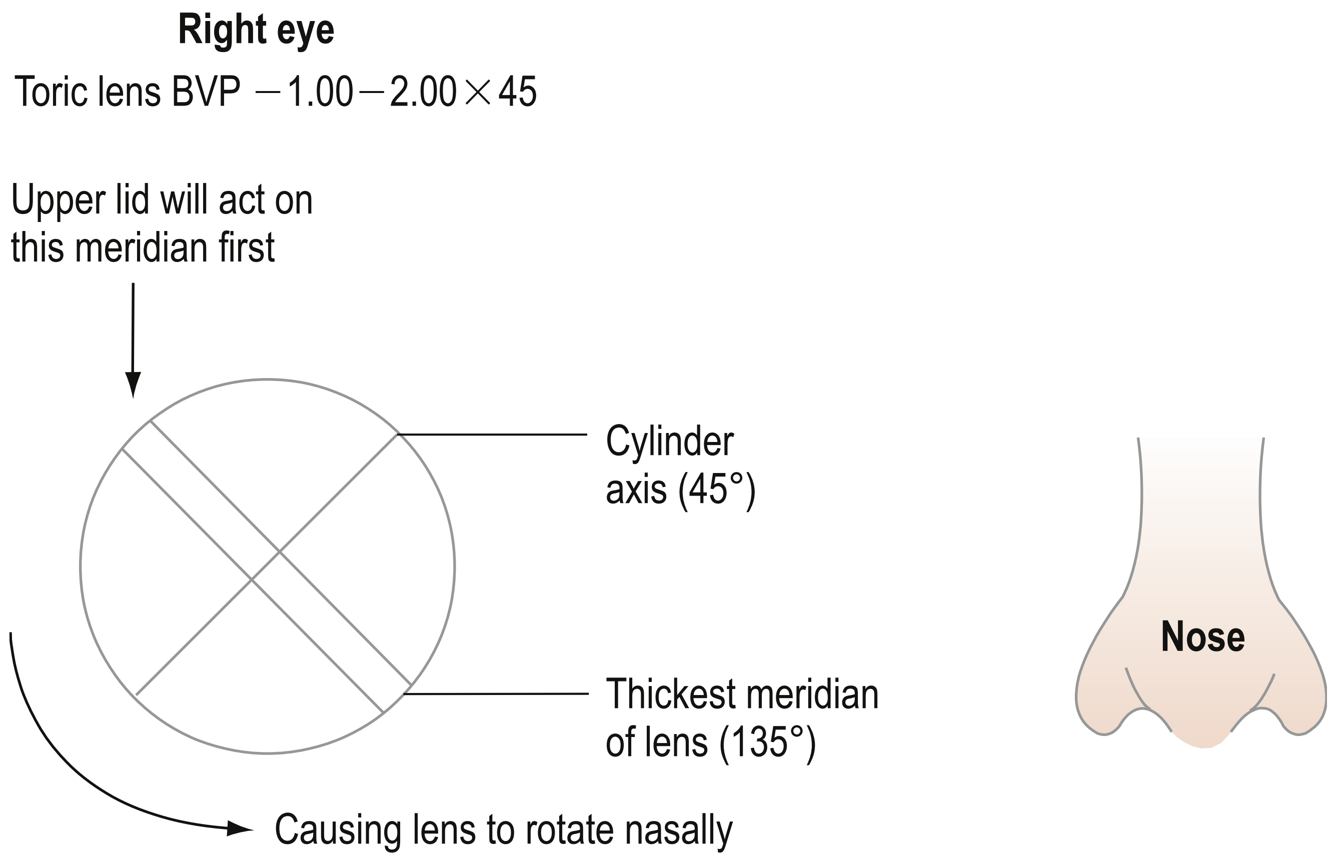
Right eye
Toric lens BVP −1.00−2.00×45
Upper lid will act on this meridian first
Cylinder axis (45°)
Thickest meridian of lens (135°)
Nose
Causing lens to rotate nasally

Fig. 9.4 The effect of lid action on lens rotation for a soft toric lens with the prescription of −1.00/−2.00×45 being worn in the right eye. As the upper lid comes down, it will first act on the lens (and the 135° meridian) at around the 10 o'clock position on the cornea. The downward motion on the lens at this point will cause it to rotate nasally. BVP = back vertex power.

ALLOWING FOR LENS ROTATION

If it is expected that the soft toric lens to be ordered will rotate when placed on the eye of the patient, then an allowance must be made for this rotation, otherwise the cylinder axis of the lens in situ will not adopt the correct orientation for the ocular correction. When allowing for nasal rotation in the right eye, the amount of rotation should be subtracted from the required cylinder axis and vice versa for the left eye. When allowing for temporal rotation in the right eye, the amount of rotation should be added to the required cylinder axis and vice versa for the left eye. Hence:

- If left eye and nasal rotation: add.
- If left eye and temporal rotation: subtract.
- If right eye and nasal rotation: subtract.
- If right eye and temporal rotation: add.

The acronym LARS (left add, right subtract) – relating to nasal rotation of the inferior aspect of the lens – can be quite useful.

Many practitioners work on the principle that clockwise rotation necessitates adding the allowance for rotation to the required cylinder axis, and anticlockwise rotation requires subtracting the allowance for rotation to determine the final cylinder axis. Hence:

- If clockwise rotation: add.
- If anticlockwise rotation: subtract.

If, at the dispensing or aftercare visit, the lens rotation is not what was expected (but the lens location is stable), simply reorder the lens with the revised allowance for lens rotation. Generally, rotational stability is a more important factor than the degree of rotation. Lenses that give suboptimal but stable acuity are more likely to be acceptable than those that give moments of clear vision followed by moments of poor vision as the lens rotates.

MEASUREMENT OF LENS ROTATION

Soft toric lenses will usually have markings on the lens at a specific reference point so the degree of rotation can be assessed when the lens is on the eye. The markings may be in the form of laser trace, scribe lines (Fig. 9.5), engraved dots or ink dots (Fig. 9.6).

The lens markings do not represent the cylinder axis; they are simply a point of reference with regard to which the rotation of the lens can be assessed. They may either be at the 6 o'clock position of the lens or in the horizontal lens meridian at the 3 and 9 o'clock positions. The latter situation is preferable as the markings can then be observed without having to retract the lower eyelid (which would interfere with the dynamic stabilizing forces that normally act to orient the lens). In addition, having two widely spaced markings about 14 mm apart at the 3 and 9 o'clock positions, as opposed to one mark or a set of marks at the 6 o'clock position, makes it easier to quantify the angle of rotation. Many laboratories that opt for the 6 o'clock indication provide three lines on their lenses, each separated by the same known angle, thus also facilitating a determination of lens rotation. Generally, lenses with markings at the 6 o'clock position are those with asymmetrical dynamic stabilization where it is important for the larger, thinner peripheral zone to be oriented superiorly for optimal lid interaction.

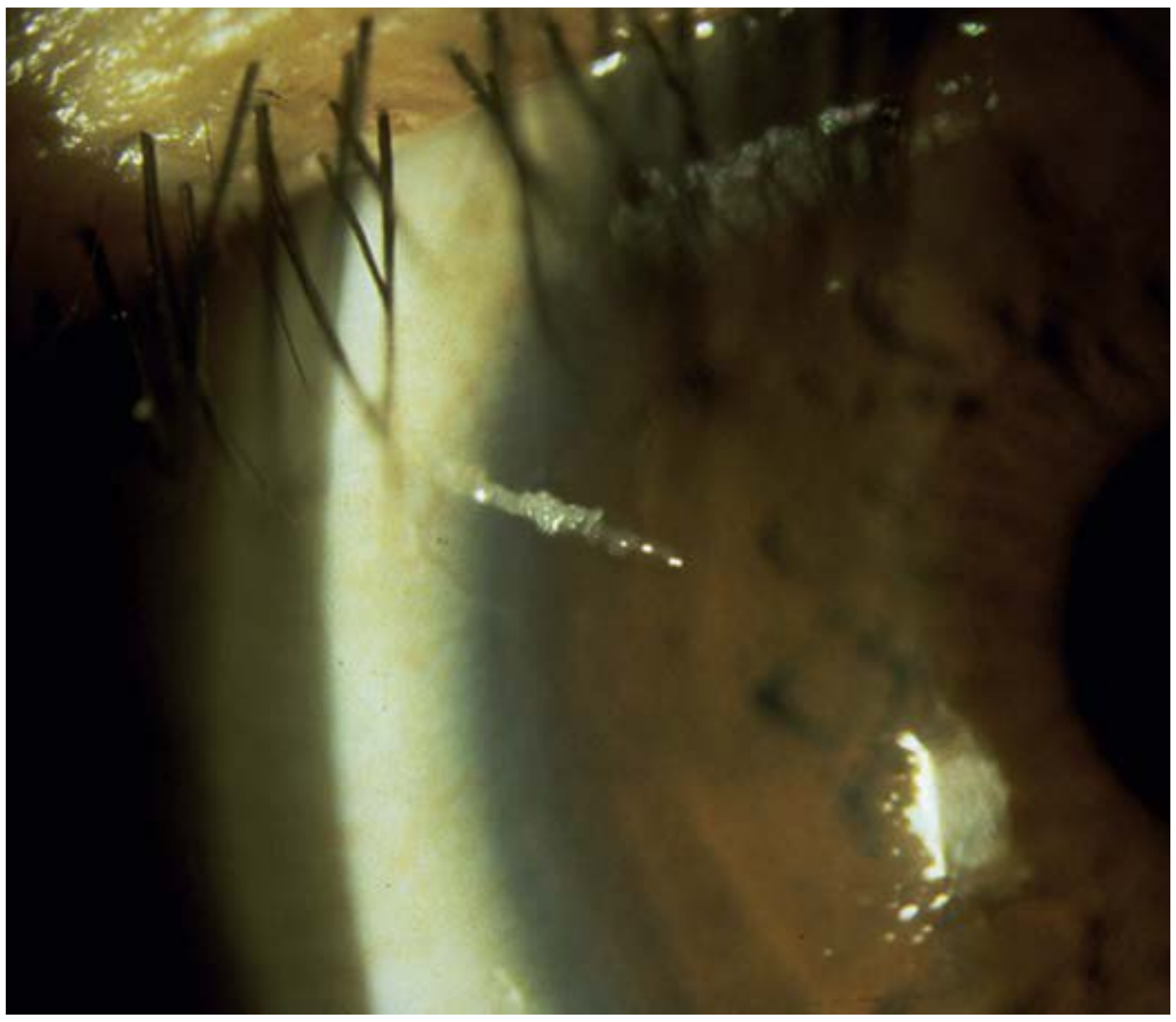

Fig. 9.5 Scribe line on soft toric lens. This lens has two scribe lines as markers, with the reference points being at the 3 and 9 o'clock locations (only the 9 o'clock mark is visible here). Debris has accumulated in the scribe line – a common site for deposit formation.

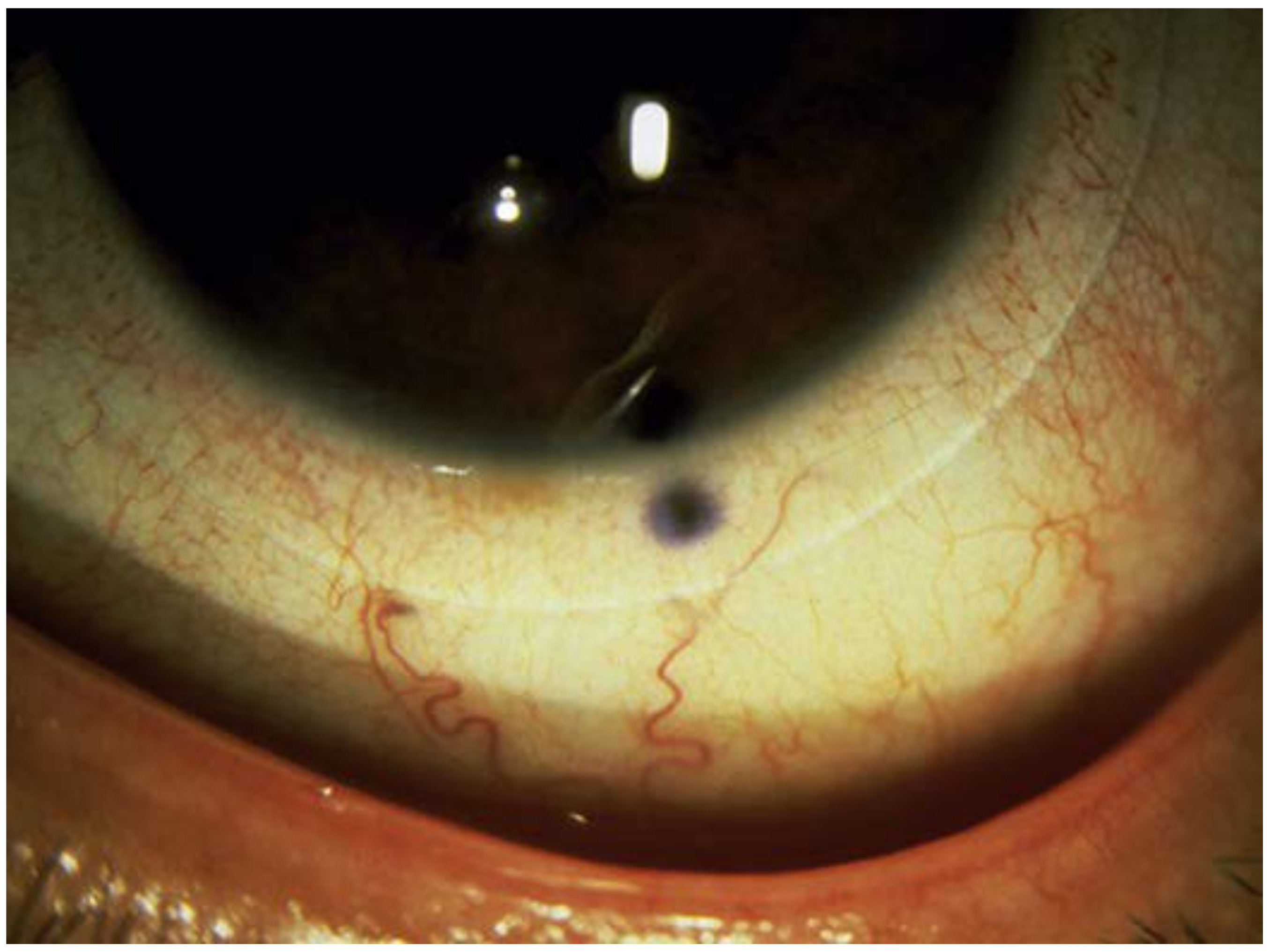

Fig. 9.6 Soft toric lens with two ink dots, one above the other, as markers for the 6 o'clock reference point. The upper ink dot is only just visible against the dark iris. Two dots are used to help with lens identification; the lens in the other eye has just one ink dot. This lens is exhibiting about 10° nasal rotation.

Estimation is a straightforward and reasonable technique for assessing the degree of lens rotation, made simpler if the practitioner remembers that there is 30° between each hour on a clock face. Clinical experience has shown that this is a satisfactory method of assessing lens rotation, with errors more likely to occur when evaluating higher amounts of lens rotation (Snyder and Daum, 1989).

When assessing lens rotation, it is important to realize that it is the angular orientation of the marker on the lens that is significant and not the position of the marker on the cornea. Fig. 9.7 shows a soft toric lens on a left eye with the marker indicating that the lens is rotating nasally by about 20° (given that the reference point for the marker is the 6 o'clock position). However, a closer look at the marker reveals that it is vertically oriented, the expected orientation if the lens was not rotating. In this case, the apparent nasal rotation is due to a nasal decentration of the contact lens.

DETERMINING LENS MISALIGNMENT

The usual method of determining lens misalignment is simply to estimate the degree of lens rotation by observing the location of the soft toric lens on the eye. This value is then compared with the expected lens rotation that has been incorporated into the BVP of the contact lens. The difference between the actual and expected values represents the degree of lens misalignment.

An SCO can also be used to determine the degree of lens misalignment. The lens misalignment is deduced by calculating the effective BVP of the lens on the eye ($\text{BVP}_{\text{in situ}}$). The SCO obtained over the mislocating soft toric lens is subtracted from the ocular refraction (Oc Rx) of the patient (Lindsay et al., 1997). That is:

$$\text{BVP}_{\text{in situ}} = \text{Oc Rx} - \text{SCO}$$

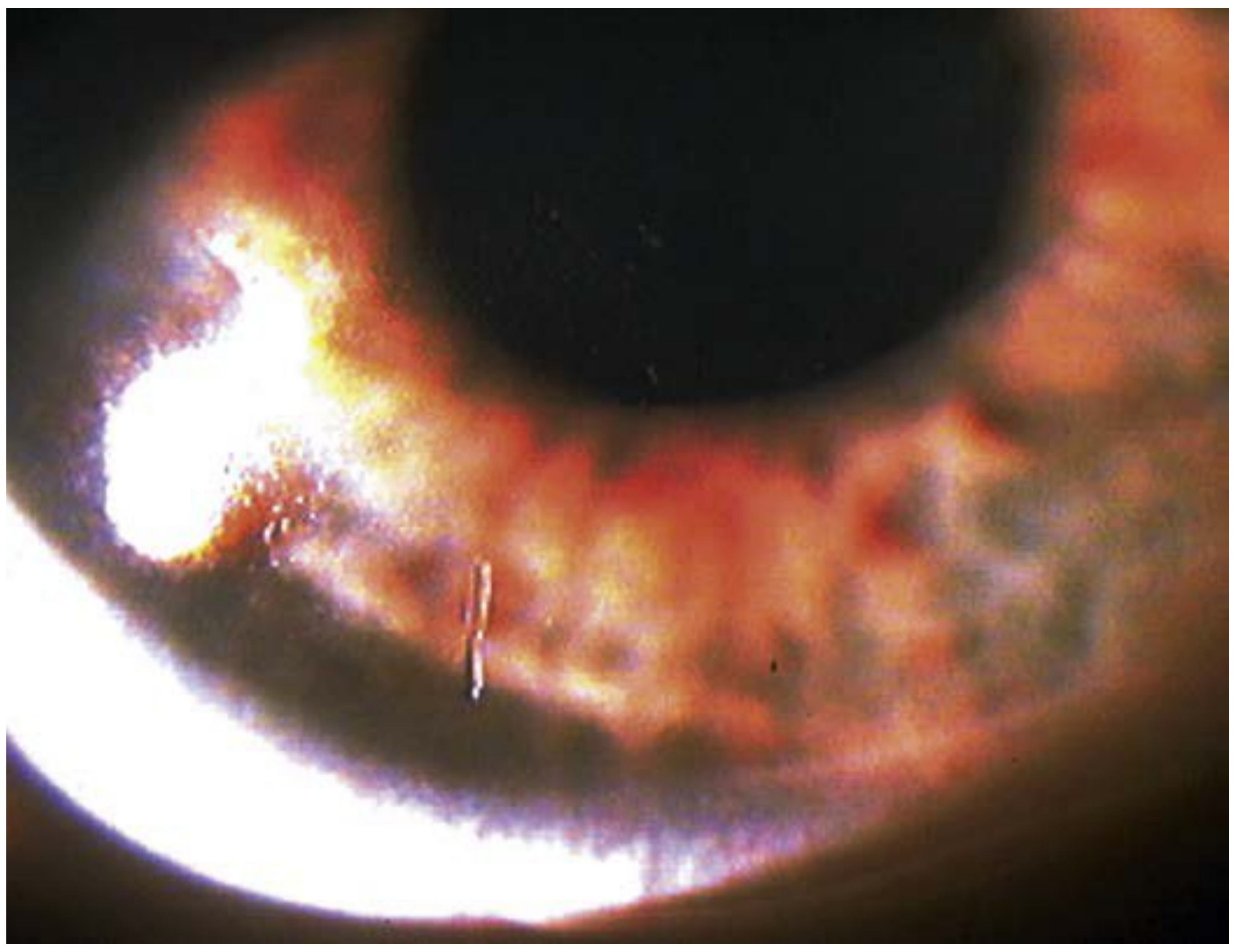

Fig. 9.7 False appearance of lens rotation resulting from a decentred contact lens that has not actually rotated.

Calculating the $\mathrm{BVP}_{\mathrm{in\ situ}}$ will require the resolving of obliquely crossed cylinders and this is best done by matrix optics (Long, 1976; Keating, 1980) using the following method:

1. Express both the spherocylindrical ocular refraction and the SCO in dioptric power matrix form (F), whereby:

$$F = \begin{vmatrix} S + C\sin^2\theta & -C\sin\theta\cos\theta \\ -C\sin\theta\cos\theta & S + C\cos^2\theta \end{vmatrix}$$

   where S is the sphere power, C is the cylinder power and θ is the axis (in radians) of the cylinder.

2. Subtract the dioptric power matrix for the refraction from the dioptric power matrix for the ocular refraction, to obtain the dioptric power matrix, F_r, for the $\mathrm{BVP}_{\mathrm{in\ situ}}$:

$$F_r = \begin{vmatrix} S_r + C_r\sin^2\theta_r & -C_r\sin\theta_r\cos\theta_r \\ -C_r\sin\theta_r\cos\theta_r & S_r + C_r\cos^2\theta_r \end{vmatrix}$$

3. Convert the matrix form of the $\mathrm{BVP}_{\mathrm{in\ situ}}$ back to spherocylindrical notation using the following formulae:

$$\text{If the lens power matrix is} \begin{vmatrix} a_{11} & a_{12} \\ a_{21} & a_{22} \end{vmatrix}$$

$$\text{trace (t)} = a_{11} + a_{22} \text{ and}$$

$$\text{determinant (d)} = (a_{11}a_{22}) - (a_{12}a_{21})$$

   To convert the matrix form of the $\mathrm{BVP}_{\mathrm{in\ situ}}$ back to spherocylindrical notation, the sphere power, cylinder power and cylinder axis of the $\mathrm{BVP}_{\mathrm{in\ situ}}$, S_r, C_r and θ_r, can be determined as follows:

$$S_r = \frac{(t - C_r)}{2}$$

$$\theta_r = a\tan\frac{(S_r - a_{11})}{a_{12}} \times \frac{180}{\pi} \text{ (where } \theta_r \text{ is in degrees)}$$

$$C_r = -\sqrt{t^2 - 4d}$$

The minus sign before the radical symbol simply means that the final solution will be in minus cylinder form.

These formulae can easily be incorporated into a spreadsheet (Table 9.2) that can then be quickly utilized in clinical practice.

Once the $\mathrm{BVP}_{\mathrm{in\ situ}}$ has been determined, any degree of lens misalignment can then be identified, along with any errors in the power of the manufactured lens, by comparing the $\mathrm{BVP}_{\mathrm{in\ situ}}$ with the BVP specified for the contact lens.

For example, consider a soft toric lens being fitted to the left eye of a patient. The ocular refraction is −3.00/−2.00 × 10. The specified BVP of the contact lens is −3.00/−2.00 × 20, so this prescription incorporates an allowance for 10° nasal rotation. An SCO with this lens yields +0.50/−1.00 × 47.5. Solving for $\mathrm{BVP}_{\mathrm{in\ situ}}$ gives −3.00/−2.00 × 175. The specified cylinder axis was 20°; however the effective cylinder axis on the eye is 175°. Therefore the lens is exhibiting 25° nasal rotation on the eye (instead of the expected 10° nasal rotation). To allow for this 25° nasal rotation, the contact lens would now have to be reordered with a cylinder axis of 35° to achieve the target cylinder axis on the eye of 10°.

If visual acuity is not improved by the SCO, the cause of the suboptimal acuity may be a poorly fitting lens, a lens of poor quality (possibly due to significant deposition on the lens surface) or some form of ocular pathology (Myers et al., 1990).

Planned Replacement of Soft Toric Lenses

Many clinicians initially treated planned replacement (i.e. disposable) soft toric lenses with scepticism because of concerns about on-eye performance and reproducibility (Lindsay, 2006); however, presently most soft toric contact lenses are prescribed on a disposable basis, with a recent survey revealing that less than 1% of new soft toric lens fits did not involve any planned lens replacement (Morgan et al., 2016). The majority of disposable lenses are replaced at monthly, two-weekly or daily intervals and disposable soft toric lenses are available in these three modalities, as well as in both conventional hydrogel and silicone hydrogel materials. As noted in Chapter 20, the rationale for the planned replacement of soft contact lenses is based on the tenet that cleaner lenses should produce fewer adverse ocular effects.

TABLE 9.2 Spreadsheet for Determining Soft Toric Lens Misalignment

	A	B	C	D	E
1		SPHERE	CYLINDER	AXIS	
2					
3	Oc Rx	−3	−2	10	=D3/57.2958
4	MATRIX	=B3+C3*(SIN(E3)^2)	=−C3*SIN(E3)*COS(E3)		
5		=−C3*SIN(E3)*COS(E3)	=B3+C3*(COS(E3)^2)		
6	OR	0.5	−1	47.5	=D6/57.2958
7	MATRIX	=B61C6*(SIN(E6)^2)	=−C6*SIN(E6)*COS(E6)		
8		=−C6*SIN(E6)*COS(E6)	=B6+C6*(COS(E6)^2)		
9	SU	=B4-B7	=C4-C7		
10		=B5-B8	=C5-C8		
11	TRACE	=B9+C10			
12	DET	=(B9*C10)−(B10*C9)			
13	BVPin situ	=(B11-C13)/2	=−SQRT((B11^2)−4*B12)	=IF(57.2958*ATAN((B13-B9)/C9)>0, 57.2958*ATAN((B13-B9)/C9), 180+57.2958*ATAN((B13-B9)/C9))	
14					

Virtually all disposable soft toric lenses are produced as a stock range of lenses encompassing a certain number of cylindrical powers (such as −0.75, −1.25 and −1.75 D), a set choice of spherical powers (for example, from +6.00 to −9.00) and cylinder axes in 5° or 10° steps – usually the latter – most often covering the complete spectrum from 0° to 180°. The choice of back optic zone radius and total lens diameter for these lenses is also usually limited; hence, given that the contact lens practitioner has chosen to use a particular type of disposable soft toric lens, the main decision in fitting and prescribing these lenses generally relates to the specification of BVP.

One of the advantages associated with the use of disposable soft toric lenses is that it is usually possible to undertake a lens-wearing trial on a prospective patient using a disposable soft toric lens with the appropriate BVP. This allows the practitioner to ascertain more accurately whether the cylinder axis of the soft toric lens in situ will adopt the correct orientation for the ocular correction. At the same time, the practitioner is also able to determine whether the patient can wear the lens comfortably without any adverse effect on the eye.

Limitations of Toric Soft Lenses

There will be a certain number of cases encountered in clinical practice where soft toric lenses are either less likely to be successful or do not represent the best option for the prospective contact lens patient. In these situations, the practitioner should take extra care when prescribing soft toric lenses.

LOW SPHERICAL COMPONENTS

Patients who are fitted with soft toric lenses that contain a low spherical component, for example +0.25/−2.50 × 180, are often very critical of axis alignment because the astigmatism is the most significant component of their refractive error. In addition, with some of the older soft toric lens designs, the thickness differentials (to aid lens location) that can usually be achieved are reduced with small spherical components (Hanks and Weisbarth, 1983).

OBLIQUE CYLINDERS

As previously discussed (Holden, 1975; Gundel, 1989), soft toric lenses incorporating oblique cylinders, for example −2.00/−2.00 × 45, may show poorer stability due to complex lid lens interactions.

LARGE CYLINDRICAL COMPONENTS

Lens rotation becomes more significant as the degree of cylinder is increased. For example, a patient with a toric lens incorporating a 1.25 D cylinder may be able to tolerate a 5° rotation from the expected lens location, whereas a toric lens patient with a 3.50 D cylinder will probably notice a significant drop in vision for the same degree of rotation off-axis.

IRREGULAR ASTIGMATISM

No form of soft toric lens is able to correct irregular astigmatism. Patients with astigmatic errors of this nature are usually corrected with some form of rigid contact lens.

PHYSIOLOGICAL CONSIDERATIONS

Improvements in toric lens design have led to an overall reduction in the thickness of most soft toric lenses. This decrease in lens thickness has led to a reduction in the number of physiological problems encountered with soft toric hydrogel lenses. Despite this, the overall thickness of a soft toric lens can be significantly greater than that of a soft spherical lens because of the addition of a cylinder and the creation of thickness differentials throughout the toric lens form. Consequently, oxygen transmissibility will be reduced – especially if the lens has not been made up in a silicone hydrogel material – and mechanical irritation increased in the thicker regions of the lens, with the result that compromises to ocular health are more likely to occur.

Conditions seen quite often with soft toric lens wear include the following:

- corneal oedema – especially in patients with hyperopic astigmatism wearing hydrogel lenses
- corneal neovascularization – usually inferior and superior and more likely in myopic patients wearing hydrogel lenses
- superior limbic keratoconjunctivitis – especially with large lenses
- conjunctival indentation – especially with tight-fitting lenses.

If corneal hypoxia is a suspected cause of any ocular changes seen with soft toric lens wear, then a sensible strategy would be to refit the patient with a soft toric lens incorporating a silicone hydrogel material so as to improve the oxygen transmissibility of the lens.

Conclusion

A large variety of soft toric lens designs are available today, incorporating a number of different stabilization techniques. As a result, the visual requirements of most astigmatic patients are readily satisfied. The fact that these products are often supplied in frequent replacement and disposable modalities means that it is also possible to make soft toric lens wear convenient and tailored to the lifestyle requirements of the patient.

Access the complete references list online at http://www.expertconsult.com.

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10

Soft Lens Care Systems

PHILIP B MORGAN

Introduction

With the very notable exceptions of daily disposable lenses and extended-wear lenses that are discarded after each period of continuous wear, all contact lenses must be subjected to some form of maintenance procedure after each use. The key elements of lens maintenance are cleaning and disinfection. Contact lenses must also be safely stored in solution until they are next worn. This chapter explores the rationale for undertaking these tasks, and reviews current lens care maintenance options.

THE RATIONALE FOR DISINFECTING CONTACT LENSES

Contact lens practitioners are acutely aware that an eye wearing a contact lens is more likely to become infected than an eye not wearing a contact lens. Brennan and Coles (1997) estimated the risk of contact lens-associated infection as being 60 times greater in a contact lens wearer than in a non-lens wearer. The reasons for this increase in risk are multifactorial, and it is worth considering these factors in the first instance as they essentially form the rationale for contact lens disinfection.

The eye has a number of inherent protective mechanisms to resist infection. These are generally successful, as can be seen in the light of work by Fleiszig and Efron (1992), who estimated that potential pathogens are present in the tear film of 5% of a population at any time, yet the prevalence of ocular-surface infection falls far short of this value. The tear film and the blinking process play an important role in the resistance of infection. Basal tear production is of the order of 1–2 μl/min and the overall tear volume is about 7 μl, which confirms the rapid turnover of tears at the ocular surface with the consequent removal of microorganisms.

Bacteria in the tear film must also breach the defence provided by proteins in the tear film such as lysozyme, lactoferrin and surfactant protein D. Furthermore, immunoglobulins such as secretory IgA, IgG, IgE and IgM can act to resist infection.

A microorganism that is able to defeat all the above systems is still hampered in its quest to invade and infect the cornea because of the various defences of the corneal epithelium. These include: tight junctions, which prevent the migration of microorganisms between epithelial cells; sloughing of cells from the epithelial surface to remove infected cells before any further harm is caused to the rest of the cornea; the active release of antibacterial factors from the corneal epithelium; and the 'filter-like' barrier provided by the basal lamina, which prevents bacteria reaching the underlying stroma (Fleiszig and Evans, 2010).

Contact lens wear adversely affects a number of these defence mechanisms. Perhaps the most significant effect is the prevention of clearance of debris and microorganisms from the ocular surface by the blinking mechanism owing to the protection offered by the contact lens. It has also been postulated that the level of fibronectin is reduced during contact lens wear, thereby increasing the likelihood of bacterial attachment to the epithelium (Fleiszig et al., 1992).

A key reason for the increase in ocular infections amongst contact lens wearers is the bioburden of microorganisms introduced to the ocular surface when lenses are applied. Indirect evidence for this is provided by the work of Radford et al. (1998), who analysed the risk factors associated with contact lens-related infections. They found that the risk of infection was significantly increased in those wearers undertaking only irregular disinfection with their contact lenses. The association of inappropriate use of the contact lens storage case (Seal et al., 1999) and a lack of handwashing (Stapleton et al., 2007) with an increased risk of contact-lens-related infections also supports the notion that contact lens wear presents an increased microbial challenge to the ocular-surface defence systems. As such, it seems clear that whilst contact lens wear renders the eye at greater risk of infection, there is good evidence that the appropriate use of suitable contact lens disinfection systems will reduce the magnitude of this increased risk.

THE RATIONALE FOR CLEANING CONTACT LENSES

There are two key reasons why a contact lens should be cleaned prior to disinfection. First, a wide variety of intrinsic and extrinsic debris can adhere to the surface of a contact lens. This can lead to lens distortion, discomfort, an unsightly cosmetic appearance (as soiled lenses can show marked discoloration clearly visible to an onlooker), ocular-surface and eyelid pathology and vision loss (Gellatly et al., 1988). Lens cleaning can mitigate against these problems. Cho et al. (2009) found rinsing to be ineffective in removing loosely bound deposits on lenses compared with rubbing. Lens deposits are discussed in depth in Chapter 19. Second, cleaning acts to enhance the disinfection process by reducing the levels of microorganisms on the contact lens. Shih et al. (1985) demonstrated this by contaminating contact lenses with an organic load plus live cells of Pseudomonas aeruginosa or Staphylococcus epidermidis. When lenses were rinsed for 10 seconds, contamination was reduced from 1 million colony-forming units (cfu) per lens to less than 3000 cfu per lens. When the lenses were rubbed with the index finger in the palm of the hand for 10 seconds with three drops of cleaner on each side before the rinsing process, there was a reduction to less than 300 cfu per lens (Fig. 10.1). The importance of contact lens cleaning is supported by the epidemiological work of Radford et al. (1995), who demonstrated that the risk of infection was about three times greater in patients who cleaned their lenses less than twice per week compared with those who achieved at least this

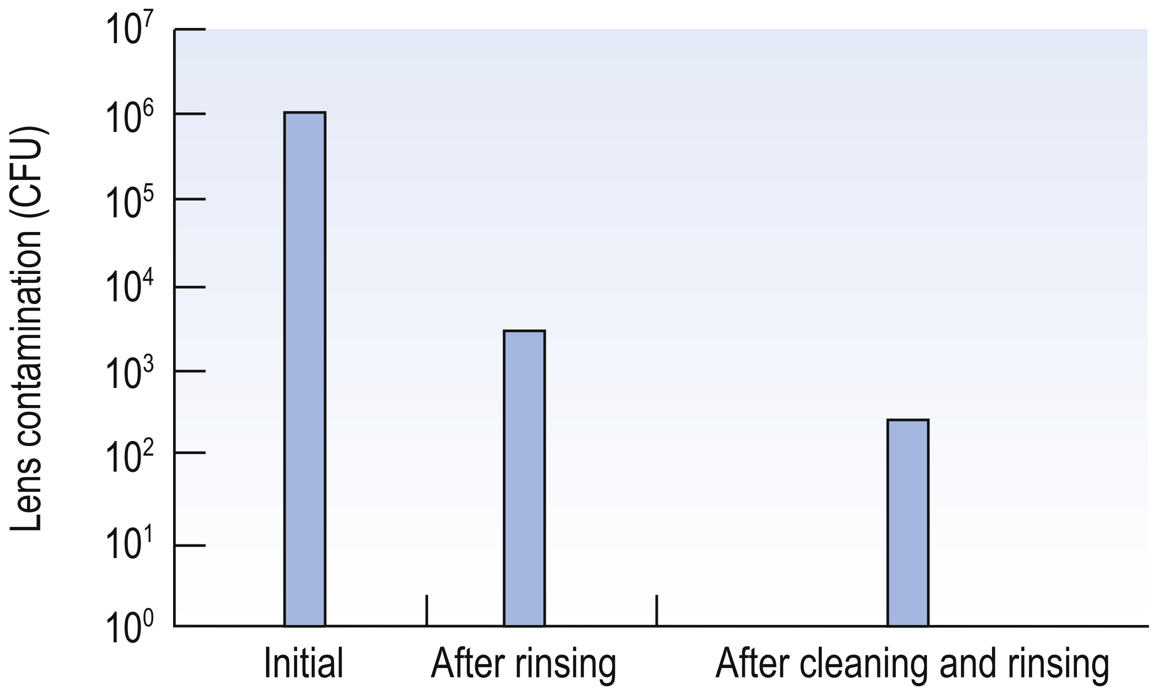


Fig. 10.1 Effect of lens rinsing and cleaning on bacterial bioburden. (Adapted from Shih, K. L., Hu, J. & Sibley, M. (1985). The microbiological benefit of cleaning and rinsing contact lenses. Int. Contact Lens Clin., 12, 235–242.)

frequency of cleaning. Zhu and co-workers (2011) have demonstrated that 'rubbing and rinsing' with a contact lens solution is more effective in removing pathogenic microbes from a lens surface than rinsing alone or indeed when no treatment is employed. Accordingly, it would seem prudent to recommend that all contact lens care systems include a rub and rinse step as part of the hygiene regimen.

THE EVOLUTION OF SOFT LENS CARE SYSTEMS

Historically, the care of a soft contact lens was a complex and time-consuming activity for the wearer. The various steps of the lens care process were divided into separate activities with a different bottle or tablet for each. This has changed over time for two reasons: first, the introduction of multipurpose products has meant that more than one component of the lens care process could be undertaken with a single solution. Second, the commercial success of disposable and planned-replacement soft lenses in the 1990s – with the associated emphasis on patient convenience – acted as a powerful incentive for the lens care industry to reduce the complexity of the lens care process as much as possible. In some respects, such as a reduced requirement for regular enzymatic cleaning of soft lenses, this was justified. In others, such as the omission of any form of lens surface cleaning, there appeared to be a related increase in the incidence of microbial keratitis (Sarwar et al., 1993).

The great majority of soft contact lens wearers are prescribed multipurpose products. A survey in 2015 of about 23 000 contact lens fits in 34 countries demonstrated that 90% of soft lens wearers were prescribed a multipurpose product, with the remaining care systems mainly peroxide based (Morgan et al., 2016). Interestingly, evidence from the United States market points to a small upsurge in the use of peroxide care systems in recent times (Efron et al., 2015).

Lens Care Systems

PHYSICAL METHODS

The various physical methods of soft lens disinfection rely on energy being imparted to microorganisms to cause lethal cell changes. Heating was the first soft lens disinfection method approved by the US Food and Drug Administration (FDA) in 1972. Disinfection using this approach requires a temperature of 80°C to be maintained for at least 10 minutes. A representative example of one of the heating units available at this time was the Bausch & Lomb system (Fig. 10.2), which reached 96°C for a period of about 20 minutes (Mote et al., 1972). In terms of lens disinfection, the heating systems were recognized as being highly effective (Busschaert et al., 1978), even against the protozoan Acanthamoeba (Ludwig et al., 1986). Furthermore, after the initial purchase of the heat unit, the ongoing costs of operation were minimal.

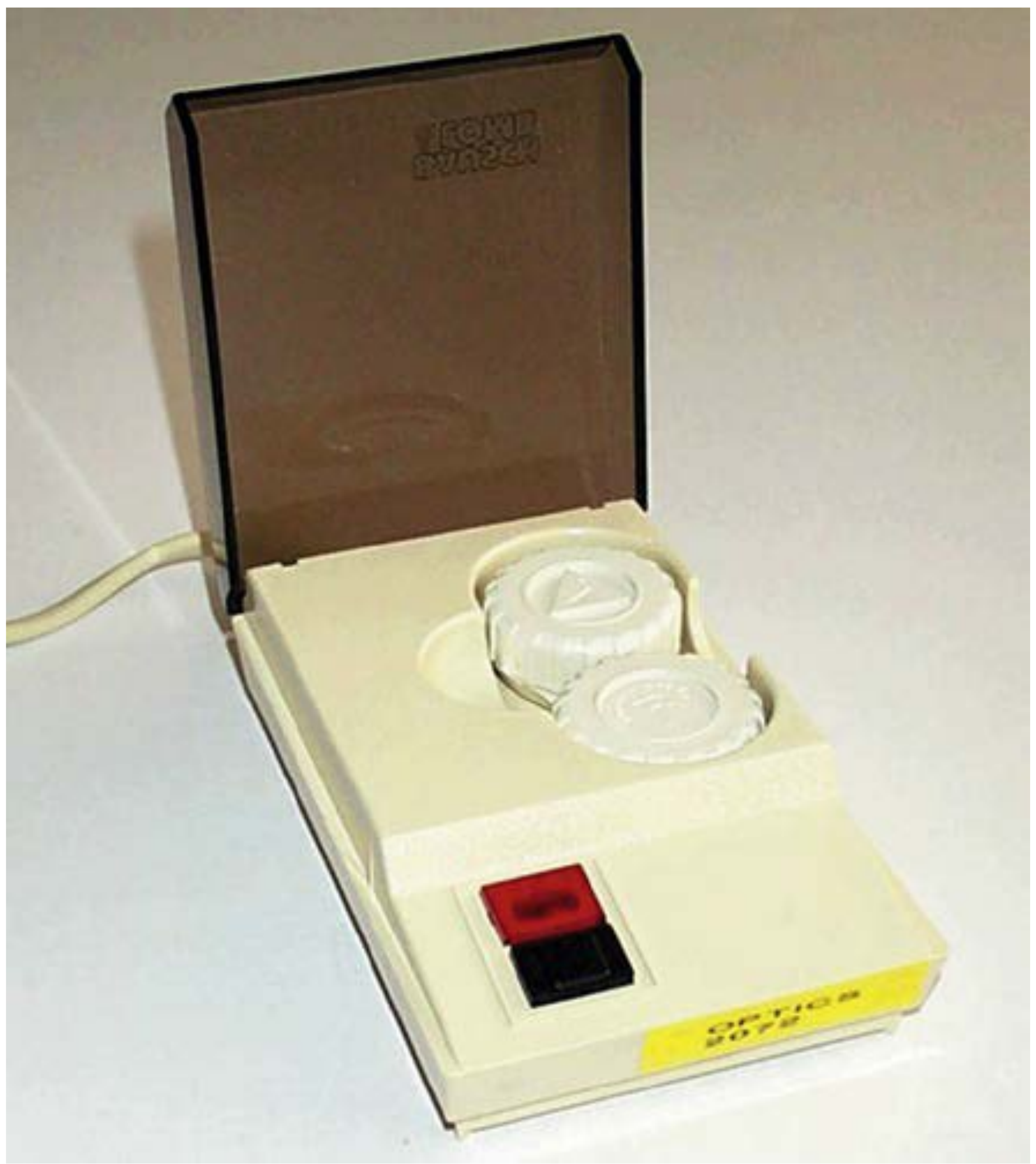


Fig. 10.2 The Bausch & Lomb lens heat unit. (Courtesy of Bausch & Lomb.)

However, there were a number of disadvantages associated with heat disinfection. In normal circumstances, the protein that spoils the surface of a soft contact lens does not denature or does so slowly; however, heating the lens will immediately denature protein with adverse clinical consequences such as reduced acuity, the potential for ocular surface reactions such as giant papillary conjunctivitis and altered physical lens parameters. With the popularity of low-water-content, non-ionic lenses in the early and mid 1970s, this was not as significant a problem as with the use of these systems with more modern, high-water-content and ionic materials that absorb much greater quantities of proteins (Maissa et al., 1998). Fig. 10.3 demonstrates how a standard single heat disinfection cycle – performed on an ionic, high-water-content lens that had been worn for 8 hours – causes the lens to turn yellow and become deformed.

The heating process was also inconvenient for many wearers. Not only did this method require a nearby source of electricity, but also the system used unpreserved saline, which did not offer any antimicrobial activity. The opportunity for microbial contamination arose if the lenses remained in the cooled saline for a prolonged period, so this disinfection system required the process to be repeated each day with fresh solution if the lenses were not used.

With the advent of planned-replacement lenses, which were generally of high water content and often manufactured from ionic materials more prone to parameter changes, the popularity of heat disinfection waned, and this technique is rarely used today.

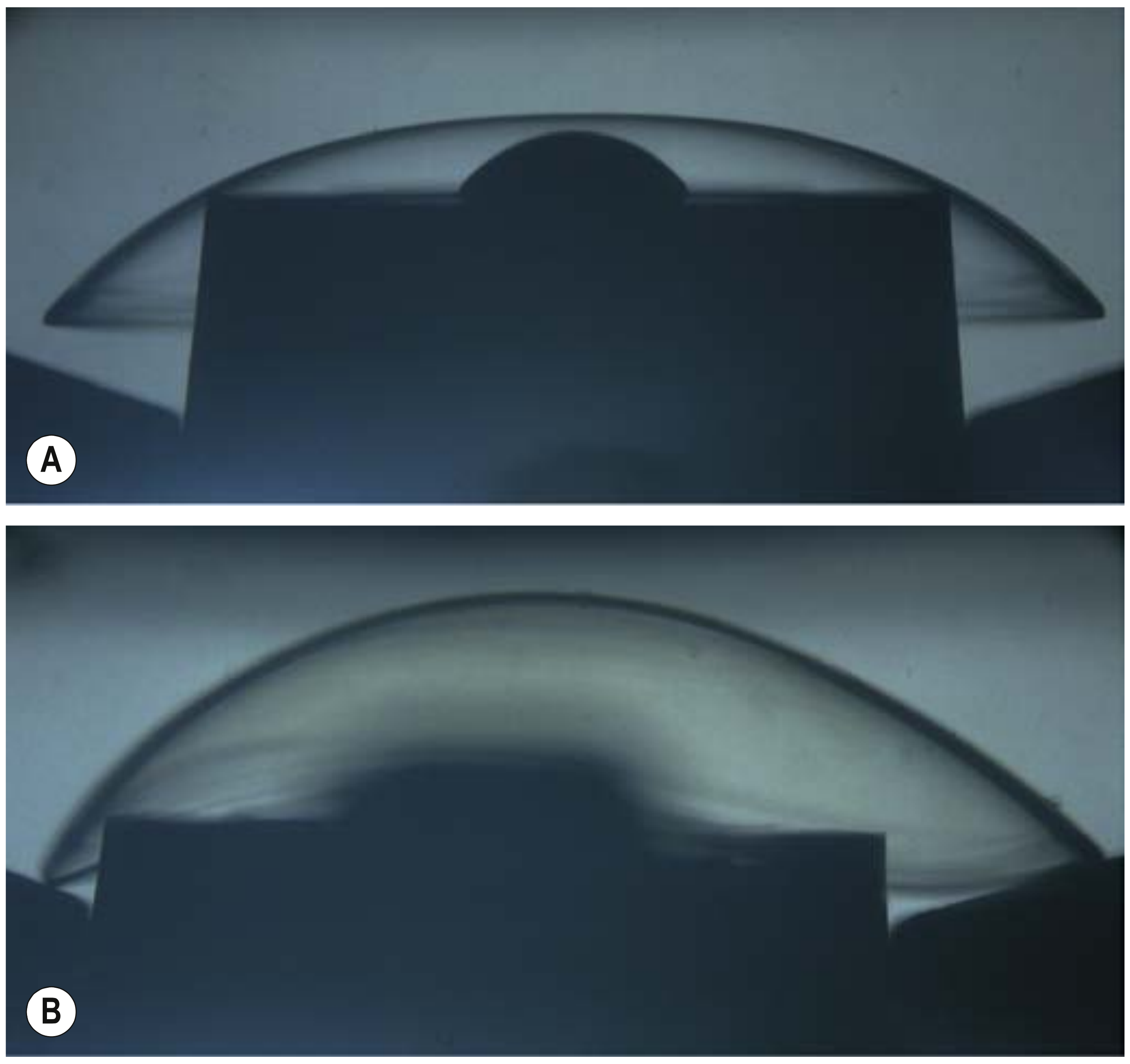


Fig. 10.3 Profile view of an ionic, high-water-content contact lens. (A) Following 1 week of extended wear. (B) Same lens as shown in (A) after one cycle of heat disinfection, which has resulted in discolouration and distortion.

Microwave irradiation has been proposed as a potentially cheap and effective method of soft lens disinfection. Harris et al. (1993a) demonstrated that, although there are some parameter changes when lenses are repeatedly irradiated with a standard 650 W microwave oven, none of these changes are clinically significant. However, as patients often need to care for their lenses in locations remote from a microwave oven, this approach is often impractical or inconvenient.

Studies on the efficacy of ultraviolet radiation for contact lens disinfection have provided equivocal results. Using radiation at 253.7 nm at an energy of 44.3 $\mu W / cm^2$, Kilvington and Scanlon (1991) found that pathogenic Acanthamoeba cysts and trophozoites survived irradiation of 22 minutes duration. Similarly, Palmer et al. (1991), using an identical system, concluded that, although the numbers of microorganisms were reduced by ultraviolet irradiation, the level of survivors was unacceptably high. On the other hand, Harris et al. (1993b) demonstrated that disinfection could be achieved at the same wavelength for a panel of bacteria using an ultraviolet lamp with a higher energy output of 950 $\mu W / cm^2$. Harris et al. (1993c) concluded that any parameter changes with this method were not clinically important.

The use of ultrasound systems for lens disinfection has also been proposed. Although such devices can be shown to have a limited disinfection effect (Efron et al., 1991a), the efficacy of ultrasound energy is limited by the physical similarity between lens material and solution, meaning that the relatively large amount of energy required to clean the lens successfully would probably damage its surface (Fatt, 1991).

CHLORHEXIDINE- AND THIOMERSAL-PRESERVED SYSTEMS

After the problems associated with heat systems became known, alternative disinfection systems were required that allowed for the simple storage of contact lenses without affecting the lens or causing irritation to the eye. Suitable early candidates were products that contained chlorhexidine gluconate or thiomersal.

Chlorhexidine is probably the most widely used biocide in antiseptics, especially for handwashing and oral products. Its action has been closely studied, and it is believed that its uptake by both bacteria and yeast is extremely rapid. Chlorhexidine damages cell walls and subsequently attacks the bacterial cytoplasmic or inner membrane, or the yeast plasma membrane (McDonnell and Russell, 1999).

Thiomersal is considered to be a less effective antimicrobial agent overall, although its action against fungi is better than that of chlorhexidine. Due to this, a combination of chlorhexidine gluconate and thiomersal became common in disinfectants for soft contact lenses. However, due to the absorption of these agents onto soft lenses, toxic and hypersensitivity reactions were reported when they were used clinically (Wilson et al., 1981). The build-up of these preservatives, and the subsequent leaching onto the ocular surface over time, had the potential to cause discomfort and discontinuation of lens wear (Hind, 1975). These products were ultimately superseded by others that offered a similar level of convenience and antimicrobial efficacy, and a lower adverse reaction rate.

Anthony et al. (1991) described a novel approach for a chlorhexidine system, known as OptimEyes (Bausch & Lomb). They developed a tablet that, when dissolved in tap water, provided a solution with a chlorhexidine concentration of 0.004%. The solution was shown to be effective against a panel of challenge microorganisms and also against most of the microorganisms found in tap water. This was a controversial development because this product was specifically designed for use with tap water and practitioners were concerned that contact lens wearers would consider standard tap water as an acceptable component of lens care generally. The product was simple and cheap to use, and it provided action against Acanthamoeba. Its disadvantages included the reliance on a supply of rising mains tap water and, importantly, it was contraindicated for use with FDA group IV lenses because the action of chlorhexidine is reduced with ionic lenses. With the increasing popularity of group IV lenses throughout the 1990s, the OptimEyes product did not become a mainstream soft lens care product.

CHLORINE

Chlorine-releasing agents are long established as disinfection systems for swimming pools, baby feeding equipment and medical instrumentation. In the 1980s, chlorine-releasing systems were developed for the disinfection of contact lenses. These were seen as being highly convenient owing to their ease of use, portability and low adverse reaction rate. In markets that did not have access to multipurpose solutions (MPS) when planned-replacement lenses were introduced at the end of the 1980s, these systems became very popular. Pearson (1992) reported that 26% of soft lens wearers in the UK used chlorine systems in 1991. No chlorine-releasing products are available today in the UK.

Two chlorine-releasing systems achieved market success. Alcon introduced the Softab product in the early 1980s (Fig. 10.4). This was a tablet of sodium dichloroisocyanurate that was dissolved in saline to form 3 parts per million (ppm) of chlorine. In the mid 1980s Sauflon developed the Aerotab product, which released 8 ppm chlorine. Laboratory studies suggested

Fig. 10.4 The Softab chlorine system. (Courtesy of Alcon.)

that these solutions were effective at destroying a range of microorganisms, including bacteria and fungi (Rosenthal et al., 1992). The killing action was thought to be due to the direct effect of the chlorine on some vital constituent of the cell of the microorganism, such as its protoplasm or enzyme system (Copley, 1989). However, these products became associated with an increase in contact-lens-related microbial keratitis (Radford et al., 1995, 1998). For example, the optimal use of a chlorine system was associated with about a 15-fold increase in the likelihood of Acanthamoeba keratitis compared with hydrogen peroxide or other solutions.

The association of ocular infections with chlorine solutions, despite satisfactory laboratory performance, suggests that there were problems with the efficacy of these systems with normal day-to-day usage. One issue was that the overnight dissipation of chlorine resulted in a loss of disinfecting power, so prolonged storage was not appropriate with these products. There was also evidence that the antimicrobial performance was severely reduced when lenses were soiled (Copley, 1989); this factor would not have been addressed when antimicrobial efficacy was determined by the licensing authorities. Overall, there was little margin for error when using these products; for example, Efron et al. (1991b) and Sarwar et al. (1993) reported a number of cases of corneal infection in patients who had failed to use surfactant cleaning solutions prior to chlorine disinfection. The negative publicity generated by such cases of microbial keratitis, and the widespread availability of MPS, which were also very easy to use, led to a great reduction in the use of chlorine-releasing systems throughout the 1990s.

HYDROGEN PEROXIDE

Hydrogen peroxide has been used as an antimicrobial agent for about 200 years. It is widely used medically for disinfection and sterilization and is generally available in concentrations from 3% to 90%, depending on its purpose. Hydrogen peroxide has a broad-spectrum efficacy against bacteria, viruses and yeast by producing hydroxyl-free radicals that attach to essential cell components such as lipid and proteins (McDonnell and Russell, 1999), and is often considered to be the 'gold standard' in terms of soft contact lens disinfection. For example, 3% hydrogen peroxide will kill trophozoites and cysts of Acanthamoeba castellanii in 3 minutes and 9 hours of soaking, respectively (Zanetti et al., 1995). It can be chemically broken down into oxygen and water, and is therefore considered to be environmentally friendly. Hydrogen peroxide tends to decompose on standing, and it therefore needs to be stabilized, typically with phosphates or phosphorates. The use of stannate as a stabilizer has been associated with hazing of ionic lenses owing to an interaction between the stannate ions, methacrylic acid groups in the lens material and tear-derived lysozyme (Sack et al., 1989).

Although hydrogen peroxide has a high efficacy in terms of its antimicrobial action, it is toxic to the eye, and requires neutralization before a lens that has been placed in hydrogen peroxide can be worn comfortably. Paugh et al. (1988) demonstrated that conjunctival hyperaemia was induced by levels of hydrogen peroxide greater than 200 ppm and that concentrations in excess of 100 ppm were associated with subjective stinging. Interestingly, these authors could not demonstrate any corneal or conjunctival staining with the highest concentration of hydrogen peroxide studied in their study (800 ppm). Changes in epithelial cell activity have been noted in the presence of concentrations as low as 30 ppm (Tripathi and Tripathi, 1989).

Storage in hydrogen peroxide has been reported to alter lens parameters. Bruce (1989) noted a temporary reduction in lens hydration after prolonged lens storage in hydrogen peroxide. High-water ionic lenses (FDA group IV) appear to be most susceptible to changes in diameter and base curve (McKenney, 1990), although the clinical consequences of these changes are generally not significant because of their temporary nature; for example, a soaking period of 20 minutes in neutralizer returns lens parameters to their original specification within 1 hour of lens wear (Jones et al., 1993).

The approaches to neutralization have varied since the introduction of hydrogen peroxide as a contact lens disinfectant. The initial approach was to allow for the storage of the lenses in hydrogen peroxide with neutralization undertaken as a secondary process before lens application. These two-step systems were considered to provide good antimicrobial action, especially when the lens was exposed to 3% hydrogen peroxide overnight; however, the complexity of using these systems has led to a cessation of their use in many markets and they are now generally not available.

The most popular approaches for the second stage of the two-step hydrogen peroxide systems were to add a solution of either catalase or sodium pyruvate to the lens storage case after the hydrogen peroxide had been discarded to neutralize any remaining peroxide (Gyulai et al., 1987; Christie and Meyler, 1997).

The more recently popular one-step hydrogen peroxide systems negate the requirement for a separate neutralization process by the contact lens user. After the lens storage case is closed, the disinfection and neutralization steps take place without further intervention. Two approaches are common. In the first, such as in the Oxysept 1-step system (Abbott Medical Optics), the lens case is filled with hydrogen peroxide, and a coated tablet containing catalase is added. As the coating of the tablet dissolves, catalase is released into the solution, leading to neutralization of the hydrogen peroxide within about 2 hours (Christie and Meyler, 1997). A number of products use a second method of neutralization: a platinum disc. In this approach, the disc is either attached as an integral part of the lens holder or is permanently lodged in the base of the storage case (Fig. 10.5). There is a rapid neutralization over the first 2 minutes – from the original 30 000 ppm, or 3% concentration, to about 9000 ppm – followed by a slower phase to 50 ppm after 3 hours (Gyulai et al., 1987), and 15 ppm after 6 hours (Christie and Meyler, 1997) (Fig. 10.6).

Oxysept
AO SEPT
AO SEPT PLUS
HydraGlyde
Alcon
SAUFLON
Multi

Fig. 10.5 Peroxide solutions including one neutralized with a tablet (left) and others neutralized with a platinum-coated disc (Courtesy of Abbott Medical Optics, Alcon and Saufon Pharmaceuticals).

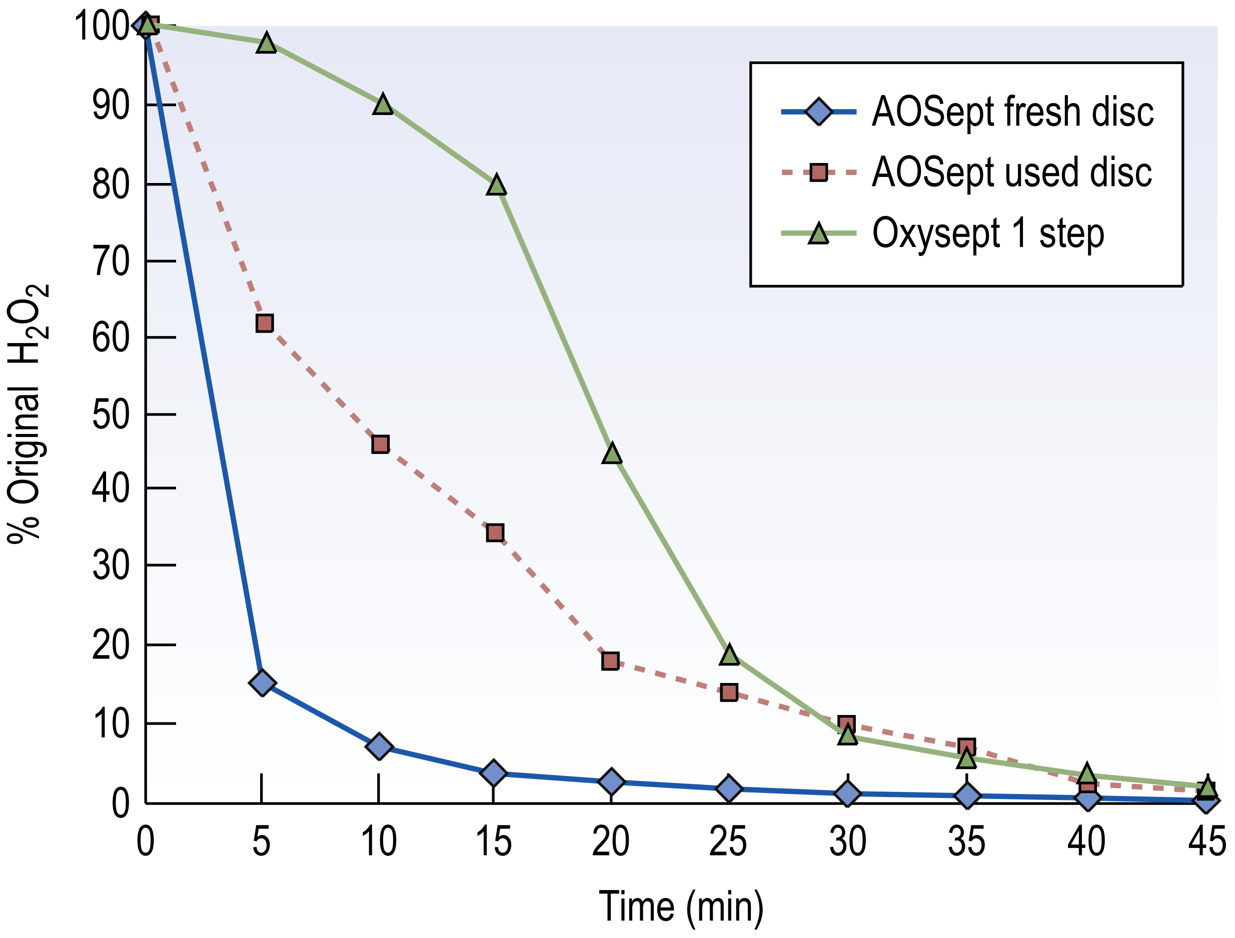


Fig. 10.6 Hydrogen peroxide is neutralized more rapidly with platinum disc systems than with tablet systems. (Adapted from Christie, C. L. & Meyler, J. G. (1997) Contemporary contact lens care products. Cont. Lens Anterior Eye, 20, S11–17.)

The trade-off for the increased convenience of a one-step system is twofold. First, as the lenses are held in neutralized solution only within a few hours of entering the case, long-term storage is not advisable as the residual solution has no antimicrobial properties. Second, the reduced time in relatively high-concentration hydrogen peroxide compared with the two-step systems affords a reduced antimicrobial power to the system. Furthermore, the speed of hydrogen peroxide neutralization differs between the tablet systems and the platinum disc systems (see Fig. 10.6). Although activity against bacteria is likely to be adequate with these systems (Stokes and Morton, 1987), the storage period is unlikely to be sufficient for efficacy against Acanthamoeba cysts (Zanetti et al., 1995). However, antimicrobial efficacy can be enhanced by appropriate lens cleaning and rinsing (Cancrini et al., 1998). It is noteworthy that the use of one-step hydrogen peroxide systems has not been associated with an increased risk of Acanthamoeba keratitis in case–control studies (Radford et al., 1995).

LENS CLEANING

One-step hydrogen peroxide systems are used with either a separate cleaning solution or an integrated surfactant cleaner, which rids the lens surface of mucus, proteins and lipids from the tear film and of other debris, such as pollutants and cosmetics, from the environment. Lens cleaning of this type has numerous clinical benefits, and wearers should be advised to clean their lenses after each use.

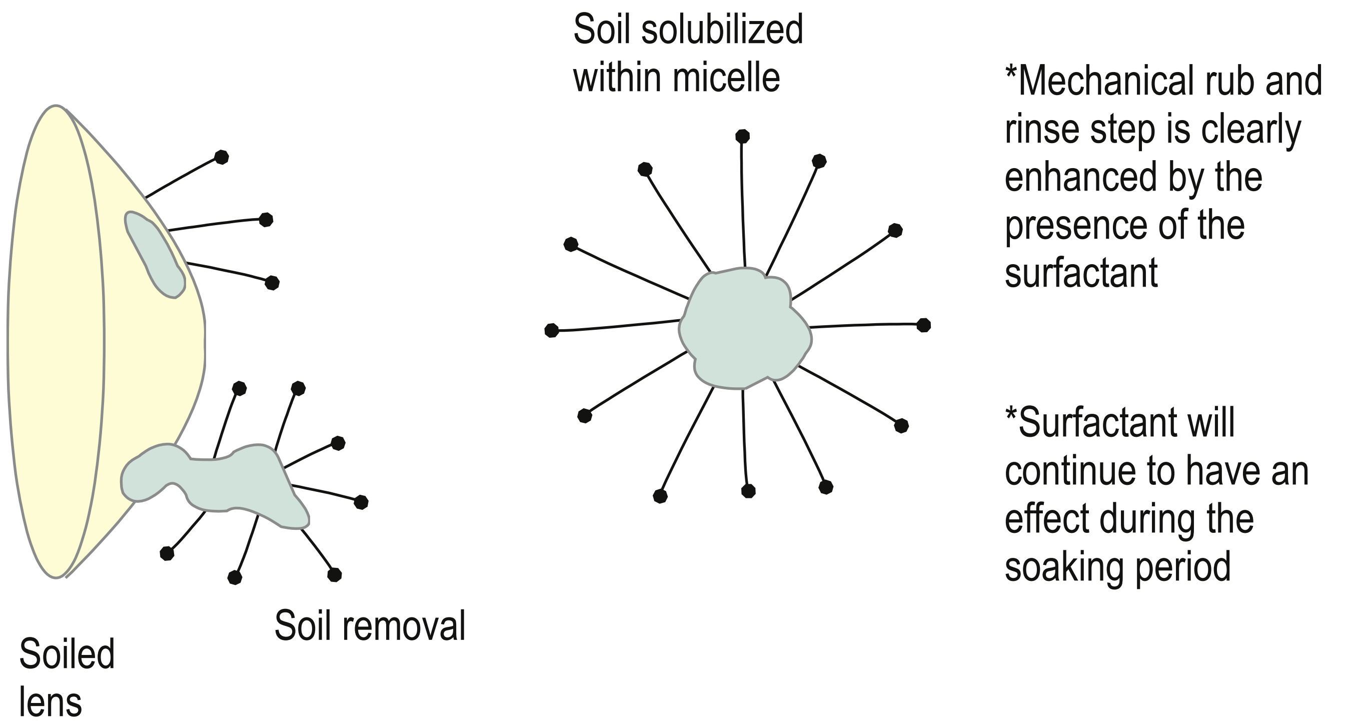

Soil solubilized within micelle
*Mechanical rub and rinse step is clearly enhanced by the presence of the surfactant
*Surfactant will continue to have an effect during the soaking period
Soil removal
Soiled lens

Fig. 10.7 Schematic representation of the action of a surfactant cleaner on a soft lens.

Such surfactant agents solubilize debris from the lens surface. Furthermore, because the surfactant molecules have a hydrophilic end and a hydrophobic end, a monolayer is formed around lipid droplets created after physical dispersion of any lipid spoilation, creating a micelle. With the hydrophobic end of the surfactant molecule 'buried' in the lipid droplet, and the hydrophobic end exposed, recoalescence of the lipid due to repulsion of the electrical charges is prevented. As the hydrophilic region is water soluble, the lipid spoilation can be emulsified (Fig. 10.7). Surfactants also act to wet hydrophobic surfaces. This is an important consideration for silicone hydrogel lenses as they are typically less wettable than conventional hydrogels. For contact lens care, non-ionic surfactants from either the poloxamer or poloxamine family are employed. Few separate ('stand-alone') surfactants are currently available owing to the popularity of multipurpose contact lens solutions.

Historically, lenses were often subjected to enzymatic cleaning, which required the use of tablets or solutions that attempted to remove protein from soft lenses. With the domination of daily disposable and frequent-replacement lenses worldwide, the use of such products is very limited.

MULTIPURPOSE SOLUTIONS

MPS account for around 90% of prescribed care regimens in Europe, Canada and Australia (Morgan et al., 2016). By definition, these products (Table 10.1) do not require the use of other auxiliary components in the lens care process. The first such products were made available for use with contact lenses in the 1980s and their popularity has increased steadily since that time.

Polyhexanide-based MPS

Most MPS contain polyhexanide (polyhexamethylene biguanide, PHMB), which was originally developed as a presurgery antimicrobial scrub and then marketed for the sanitization of swimming pools and spas. Polyhexanide is part of the same pharmaceutical family as chlorhexidine, and is active against a wide range of bacteria. The action of polyhexanide is thought to be due to its rapid attraction towards the negatively charged phospholipids at the bacterial cell surface, followed by impairment of membrane activity with the loss of potassium ions

TABLE 10.1 Constituents of Soft Lens Multipurpose Solutions (MPS)

Company	Product	Preservative (ppm)	Surfactant Cleaner	Buffer	Other Components
Abatron	Quattro	Polyhexanide (1)	Lubricare	Phosphate	EDTA
Advanced Eyecare Research	Regard	Sodium chlorite Hydrogen peroxide (100)	Pluronic		Hydroxypropyl methylcellulose (wetting agent)
Abbott Medical Optics	Complete Revitalens	Alexidine (1.6) Polyquad (3)	Tetronic 904	Borate	EDTA
Alcon	Opti-Free Express	Polyquad (10) MAPD (5)	Poloxamine	Citrate	EDTA
Alcon	Opti-Free Replenish	Polyquad (11) MAPD (5)	Tetronic 1304	Borate, citrate	Propylene glycol
Alcon	Opti-Free PureMoist	Polyquad (10) MAPD (6)	Tetronic 1304 HydraGlyde	Borate, citrate	Sorbitol Aminomethylpropanolol EDTA
Bausch & Lomb	ReNu	Polyhexanide (0.5)	Poloxamine	Borate	EDTA
Bausch & Lomb	ReNu MultiPlus	Polyhexanide (1)	Poloxamine	Borate	Hydranate EDTA
Bausch & Lomb	Biotrue	Polyhexanide (1.3) Polyquad (1)	Poloxamine	Borate	Hyaluronate Sulfobetaine EDTA
Sauflon	All-in-One Light	Polyhexanide (1)	Poloxamine	Borate	EDTA
Sauflon	Synergi	Oxipol	Poloxamer	Phosphate	Hydroxypropyl methylcellulose (wetting agent)

EDTA = ethylenediamine tetraacetic acid; MAPD = myristamidopropyl dimethylamine.

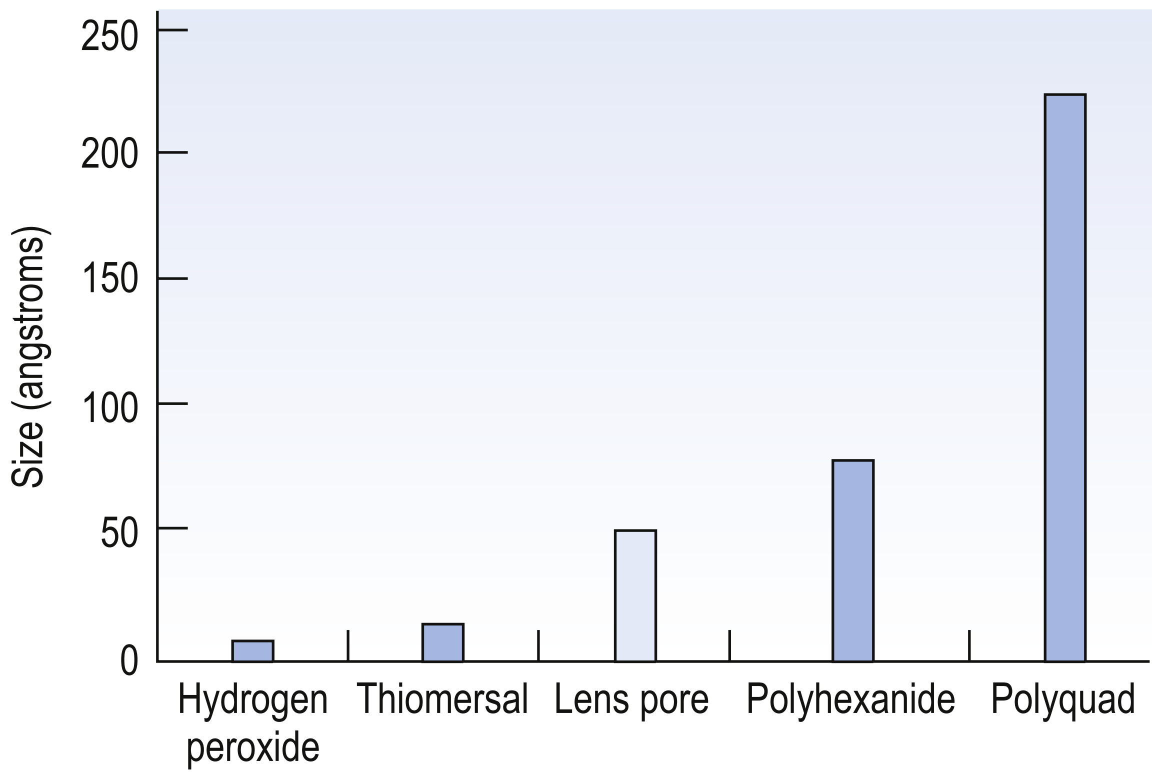


Fig. 10.8 Some active agents are smaller than a typical soft lens pore size whereas others are larger.

CyClean
ALL IN ONE
SAUFLON
light
ReNu
ReNu

Fig. 10.9 Soft lens solutions with polyhexanide as the sole disinfectant. (Courtesy of Bausch & Lomb and Sauflon Pharmaceuticals.)

and the precipitation of intracellular constituents. Polyhexanide has a larger molecular weight than chlorhexidine, which means that it is not able to enter the matrix of soft lens materials. In turn, this reduces the likelihood of the preservative reaching the ocular surface, with the potential for toxic or hypersensitivity reactions (Fig. 10.8). MPS contain polyhexanide at a range of concentrations from 0.5 to 1.0 ppm (Fig. 10.9).

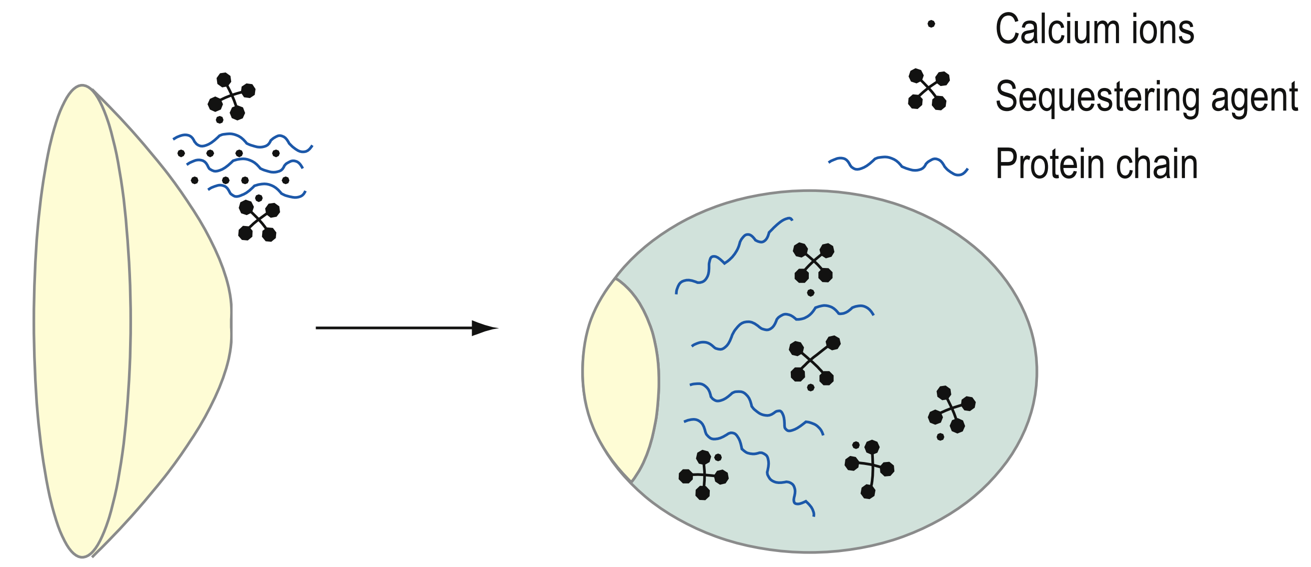
Solutions using polyhexanide as their sole disinfecting agent may also contain other key components. For example, Renu Multiplus (Bausch & Lomb) contains hydranate as a sequestering agent to reduce protein deposition. This chemical forms complexes with calcium, which can act as a bridge between the lens surface and proteins. Cyclean (Sauflon Pharmaceuticals) contains a viscosity agent and uses a novel design of lens case that allows the lens baskets to be rotated within the case to provide a cleaning action.

Polyquaternium-1-based MPS

Some MPS have polyquaternium-1 or polyquad as the preservative. This compound is derived from the same pharmaceutical family as polyhexanide – the polyquats. It is a large molecule, and has a long history of use in the cosmetics industry.

The most widely used polyquad products are the Opti-Free family, which contains polyquad and another antimicrobial agent, myristamidopropyl dimethylamine (MAPD). This contains a citrate buffer instead of the phosphate or borate buffers that are generally found in polyhexanide-based MPS. This negatively charged buffer is included in the polyquad products to reduce the adherence of polyquad to the surface of some ionic lens materials; this same property can reduce the protein deposition on soft lenses because positively charged proteins, such as lysozyme, can bind with the citrate rather than with the lens surface (Hong et al., 1994). However, citrate is not effective against lipid spoilation (Franklin et al., 1995). The antimicrobial performance of this product is claimed to be similar to disinfection with a one-step hydrogen peroxide system (Rosenthal et al., 1999).

A surfactant is typically included in MPS (both polyhexanide and polyquad based) so that they can offer a cleaning action in addition to their disinfection properties. These solutions also contain ethylenediamine tetraacetic acid (EDTA), or one of



1) Exaggerated view of protein chains bound to each other and the lens electrostatically with calcium ions as bridge

2) Close up to sequestering agent molecules interacting with calcium ions to break down the deposit bridges by sequestration

Fig. 10.10 Schematic action of a chelating agent.

Fig. 10.11 Soft lens solutions with two disinfectants. (Courtesy of Abbott Medical Optics, Alcon and Bausch & Lomb.)

its salts, as a chelating agent. A chelating agent is a substance comprised of molecules that can form several coordinate bonds to a single metal ion (Fig. 10.10). In the case of contact lens care, EDTA removes ions such as calcium, resulting in a lens-cleaning effect (protein can bind to calcium on the lens surface, and therefore increase deposition) and an antimicrobial effect (calcium ions are required for cell wall metabolism by microorganisms).

'Dual Disinfection' MPS

Whilst historically MPS have included a single active disinfectant agent, more recently launched products have tended to feature two such agents and this has led to the coining of the term 'dual disinfection'. With any single antimicrobial agent demonstrating a particular range of performance across various microorganisms, the presence of two disinfectants offers the potential for synergistic action and enhanced performance. Good examples here include Complete Revitalens (Abbott Medical Optics), which includes both polyquad and alexidine; Opti-Free PureMoist (Alcon), with polyquad and MAPD, and Biotrue (Bausch & Lomb), which incorporates polyhexanide and polyquad) (Fig. 10.11).

MULTIPURPOSE SOLUTIONS AND SILICONE HYDROGEL LENSES

The MPS products discussed above were all developed and launched when conventional hydrogels dominated the daily-wear contact lens market. Since the launch of the first silicone hydrogels specifically marketed for daily wear in 2004, there has been a dramatic increase in their use for this modality – from 3% of soft contact lenses prescribed for monthly replacement daily-wear lenses in the UK in 2004 to about 90% in 2014. Over a similar time period, there was a strong move towards recommending to contact lens wearers that lens rubbing or rinsing is no longer required, such that a majority of wearers do neither step (Morgan et al., 2011).

Fig. 10.12 Soft lens solutions containing sodium chlorite. (Courtesy of Advanced Vision Research and Saufon Pharmaceuticals.)

A silicone hydrogel material presents different challenges compared with conventional hydrogels for lens cleaning. The non-ionic nature of silicone hydrogels means that the lenses attract increased amounts of lipid and reduced quantities of protein compared with conventional hydrogels (the majority of which are ionic in nature) (Jones et al., 2003). Additionally, there have been reports of asymptomatic corneal staining when some MPS have been used with daily-wear silicone hydrogels (Jones et al., 2002), although the clinical significance of such staining is not clear. However, all the main MPS products on the market are approved for us with silicone hydrogel lenses. Two MPS with different chemistries that some practitioners prefer for silicone hydrogel lenses are Regard (Advanced Vision Research) and Synergi (Saufon Pharmaceuticals). Regard contains sodium chlorite and low-concentration hydrogen peroxide (100 ppm) for disinfection, a wetting agent and a surfactant cleaner. When exposed to light, sodium chlorite breaks down to sodium chloride and oxygen, thereby making this product autoneutralizing. Synergi is based around the oxochlorite complex, which is used in other industries for disinfection. This complex has appropriate disinfection properties for use with contact lenses and breaks down in light into sodium chloride and oxygen. Synergi also contains a surfactant cleaner and hydroxypropyl methylcellulose as a wetting agent (Fig. 10.12).

Rewetting Solutions

Contact lens wearers may complain of numerous symptoms, including dryness and general discomfort; such symptoms are the primary reasons for the discontinuation of contact lens wear (Dumbleton et al., 2013). A common method of clinical management of ocular discomfort is the prescription of soft lens rewetting solutions, which are also known by the synonyms of 'lubricants' and 'comfort drops' (Fig. 10.13). Efron et al. (1991c) found that, although these products were often well received by wearers and comfort was improved for at least 6 hours after their instillation, there was little evidence that their effect was

Wet.
Biotrue
blink
REVIVE
DUAL ACTION
blink contacts

Fig. 10.13 Contact lens rewetting solutions (Courtesy of Abbott Medical Optics, Advanced Eyecare Research and Bausch & Lomb).

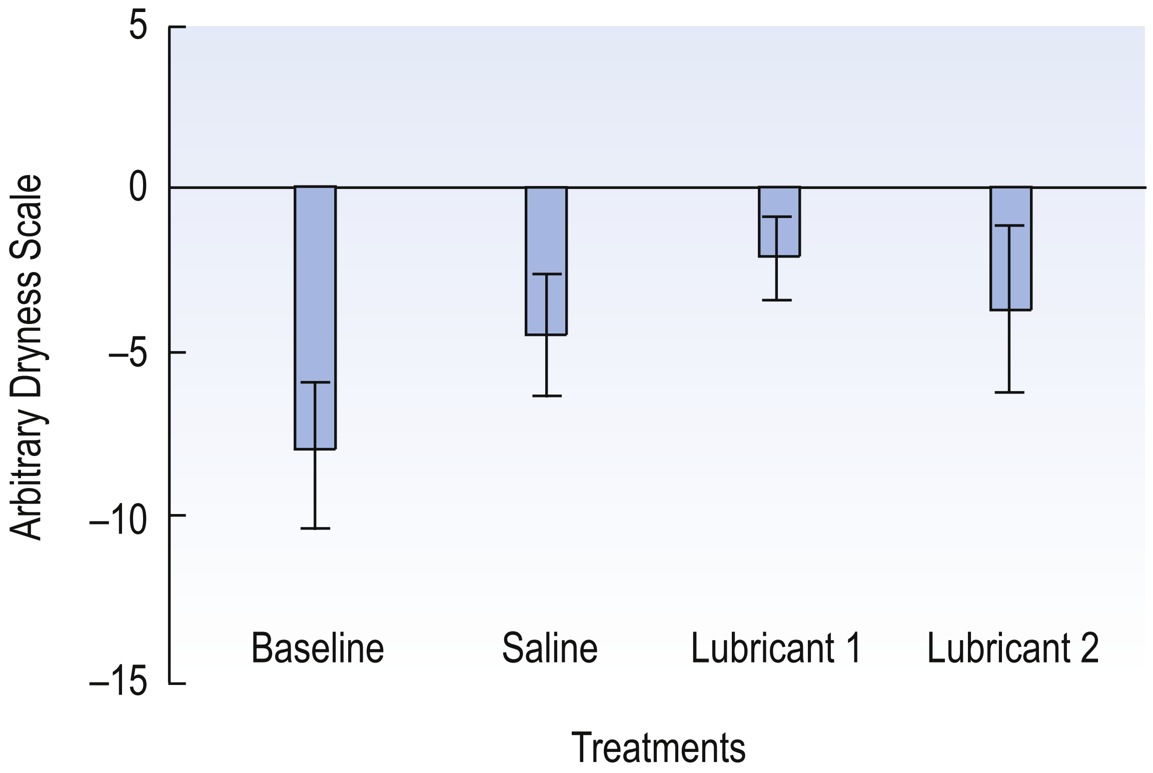


Fig. 10.14 Dryness symptoms improve with both saline and prescribed rewetting solutions. (Adapted from Efron, N., Golding, T. R. & Brennan, N. A. (1991c) The effect of soft lens lubricants on symptoms and lens dehydration. CLAO. J., 17, 114–119.)

greater than that of saline (Fig. 10.14). Furthermore, the mechanism of symptomatic relief is not clear; Golding et al. (1990) demonstrated that this was not due to an enhancement of the pre-lens tear film.

A number of products contain viscosity-increasing agents such as methylcellulose that increase the adherence of the solution to the lens and enhance the contact time of the solution at the ocular surface. Other components commonly found in rewetting solutions include sodium chloride and buffering agents.

Saline Solutions

Some contact lens wearers are prescribed a saline rinsing solution when they first commence contact lens wear. These products are particularly helpful to new wearers, who tend to handle lenses more frequently, and require more attempts at lens application, leading to increased contamination from the fingers. Some hydrogen peroxide users remove any residual hydrogen peroxide with a rinsing product to reduce any stinging on application. The rinsing process can also play a significant role in the removal of microorganisms from the lens surface (Cancrini et al., 1998).

Homemade and unpreserved saline have been associated with serious ocular-surface infections and is not recommended (Sweeney et al., 1992). Previously, contact lens solution manufacturers provided saline primarily in aerosol canisters with the pressure within the canisters preventing contamination, although it was recommended that the user ejects a small amount of saline before use as contamination of the spray tip has been associated with corneal infections (Donzis, 1997). However, this was an expensive approach to supplying saline and preserved saline solutions have gained popularity in their 'squeezy' bottle format. With these products, the active ingredient serves only to prevent contamination of the solution, rather than play any active role in contact lens disinfection. One example of these products is Bausch & Lomb saline, which is preserved with a low concentration of polyhexanide (0.3 ppm).

Relative Performance Measures

An important consideration for the contact lens practitioner when dispensing a care product is its performance in terms of cleaning and, perhaps more importantly in terms of wearer safety, disinfection efficacy.

The first safeguard for the practitioner is that, in many parts of the world, contact lens disinfectants are required to meet a number of criteria before they can be labelled and sold as such. For example, in the European Union, all such products are required to display the CE mark, which indicates that the product has displayed a minimum level of disinfecting performance and that a number of other criteria (such as satisfactory manufacturing conditions) have been met. The CE mark requires a contact lens disinfectant to meet the performance requirements of the international standard ISO 14729:3 (Microbiological Requirements for Products and Regimens for Hygienic Management of Contact Lenses; ISO, 2012). To achieve this, the product must show activity against three bacteria (Pseudomonas aeruginosa, Staphylococcus aureus and Serratia marcescens) and two forms of yeast (Candida albicans and Fusarium solani) (Fig. 10.15).

Products are first tested on a stand-alone basis. Here, the disinfectant must be able to reduce the population of each of the bacteria by 99.9% (or a three-log reduction) and the yeast by 90% (a one-log reduction). This testing is performed in laboratory conditions without the use of contact lenses; that is, there is a mixing of the test organisms with a fixed quantity of the solution under test.

If the product fails to meet the stand-alone criteria, the regimen procedure can be invoked whereby the performance of the product in a more 'real-world' situation is analysed. However, to proceed to this stage, solutions must at least have demonstrated that they are able to achieve stasis for yeast in the stand-alone test, and an overall combined five-log reduction for the three bacteria, with at least one-log reduction for each of the bacteria.

In the regimen procedure, contact lenses are inoculated with the panel of test organisms, and then treated according to the instructions provided by the manufacturer for cleaning, rinsing and soaking. To satisfy the criteria, there must be at least a four-log reduction for all the test organisms.

In order to reach the marketplace, therefore, contact lens solutions are required to achieve a set standard of performance. However, of further interest is the relative performance of the various products that are available. Although this might seem to require simply generating comparative data for a range of care products, this area is fraught with problems. For example, an approach that has been used in the past to demonstrate the disinfection capabilities of disinfectant systems is the D-value. This parameter denotes the time taken for a disinfectant product to reduce the population of an organism to 10% of its original level (a one-log reduction).

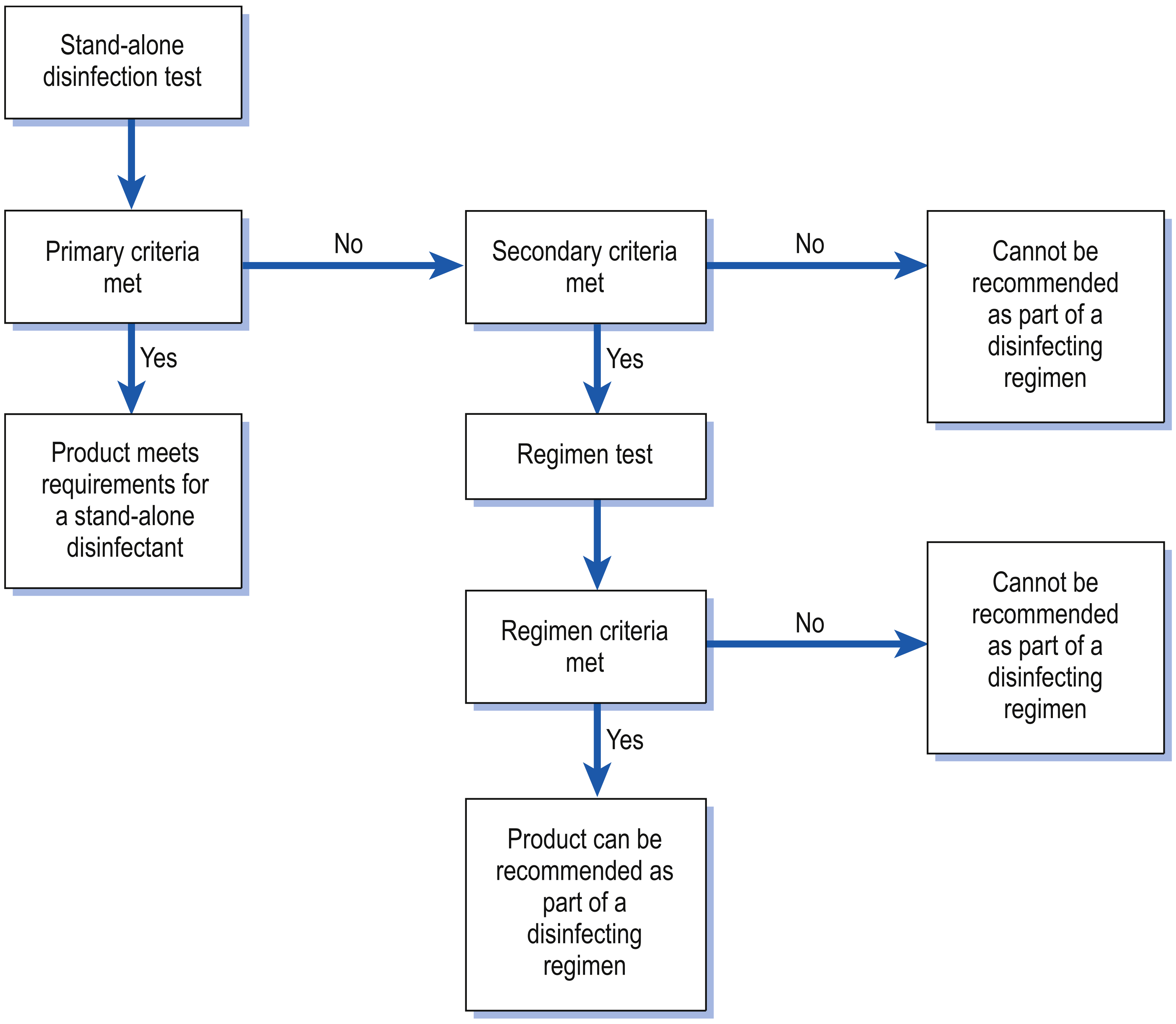

Stand-alone disinfection test
Primary criteria met
No
Secondary criteria met
No
Cannot be recommended as part of a disinfecting regimen
Yes
Yes
Product meets requirements for a stand-alone disinfectant
Regimen test
Regimen criteria met
No
Cannot be recommended as part of a disinfecting regimen
Yes
Product can be recommended as part of a disinfecting regimen

Fig. 10.15 Flow chart indicating the path by which disinfectant products are tested for ISO 14729:3.

Although this appears to be a useful indication of solution performance, there are a number of problems with its use. The D-value assumes a linear relationship between the logarithm of the number of survivors and time. However, the action of contact lens disinfectants tends to be non-linear, which suggests that the use of D-values is inappropriate and can lead to misleading representations of product performance (Sutton et al., 1991).

Another drawback to the D-value approach is that no account is made of the minimum recommended disinfection time (MRDT) recommended by the manufacturer. For example, a product may offer a one-log reduction in 20 minutes, and a three-log reduction in 1 hour; the clinical success of this product, however, must depend to some extent on the MRDT, which could be 10 minutes or 6 hours. Lowe et al. (1992) proposed a new measure of solution potency – solution power – to overcome this problem. This parameter was defined as the MRDT divided by the D-value.

A difficulty with this sort of approach is that no account is made of any cleaning or rinsing (as distinct from disinfecting) that may be employed as part of the overall care system. Some wearers may tend to omit these steps with some systems and not with others; this must have an impact on the overall disinfecting capabilities of the regimen.

Another significant problem when assessing differences between products is that different laboratory conditions and techniques can be employed. A relevant example here is the efficacy of disinfectants against Acanthamoeba. A number of variables exist when analysing the performance of products against Acanthamoeba, including the strain of Acanthamoeba used, growth conditions and contact time of the disinfectant. Indeed the results in this area are highly dependent on methodology, which has led, in part, to the efficacy of contact lens disinfectants against Acanthamoeba being omitted from ISO 14729:3.

Despite this, the effectiveness of contact lens disinfectants against Acanthamoeba is of considerable interest to contact lens practitioners. On a stand-alone basis, hydrogen peroxide is effective at destroying both Acanthamoeba trophozoites and cysts, with overnight storage in 3% hydrogen peroxide providing better performance in this regard than the shorter contact time with a one-step system (Zanetti et al., 1995). MPS have poorer antiacanthamoebal efficacy (Davies et al., 1990), although the combination of MAPD and polyquad may improve this (Rosenthal et al., 2000). In a clinical setting, cleaning and rinsing are likely to remove some Acanthamoeba (Cancrini et al., 1998). Furthermore, Acanthamoeba is thought to require the presence of bacteria to survive and grow, so antibacterial efficacy of a contact lens disinfectant will have an effect on acanthamoebal contamination.

The Lens Storage Case

An important component of the complete lens care system is the case in which the lenses and disinfecting solutions are stored. Surveys have reported that up to 77% of lens cases are contaminated with bacteria and 8% with Acanthamoeba (Gray et al., 1995). Contamination appears to be unrelated to solution type, and it is now clear that the development of microbial biofilms in contact lens cases can reduce the effect of a disinfecting solution (Fig. 10.16). Indeed, it has been speculated that long-term use of a solution might select a naturally resistant population of microbes that adapt to survive exposure to a disinfectant (Gray et al., 1995). Interestingly, some bacteria release catalase when their cell membranes are disrupted; this release could potentially act to neutralize local hydrogen peroxide and protect other bacteria within the biofilm.

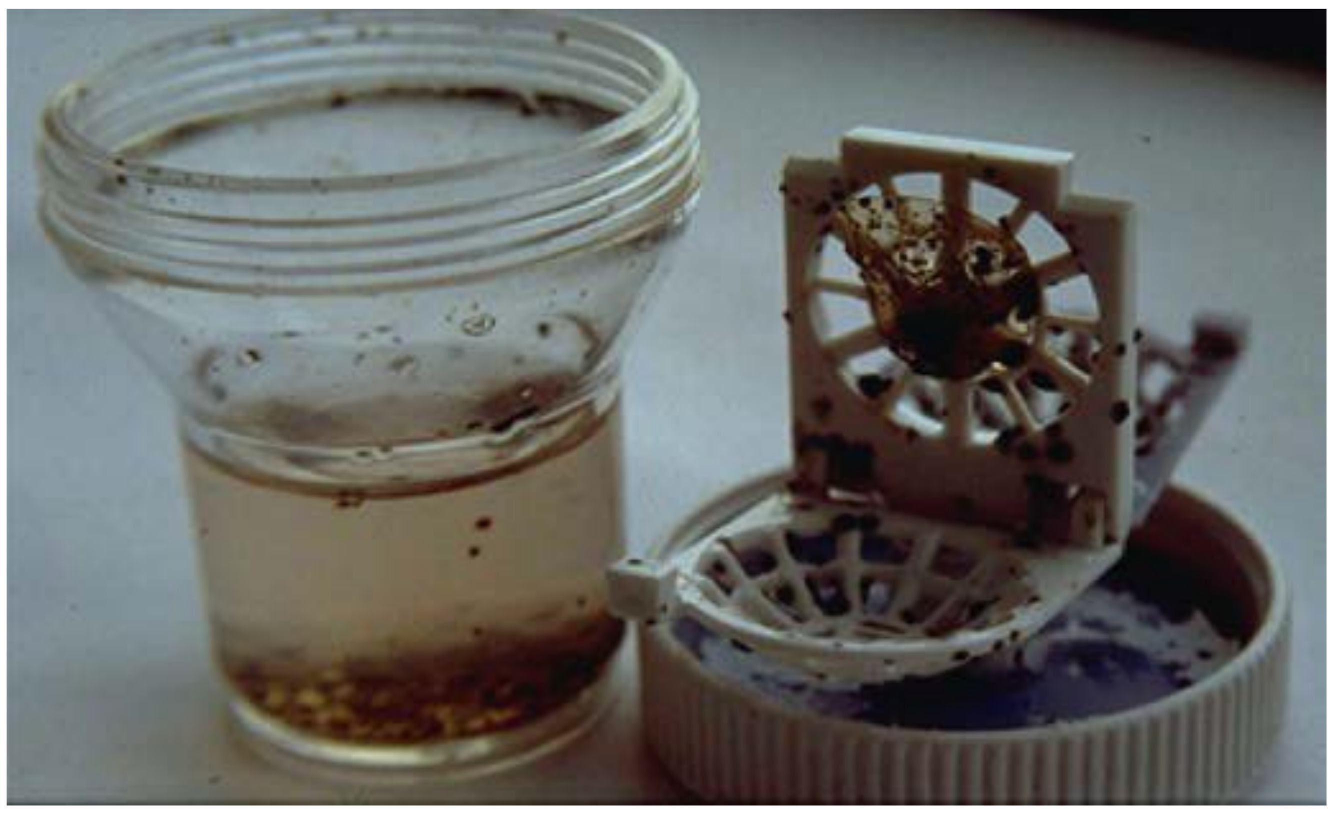


Fig. 10.16 The correct use of prescribed care systems is very important for efficient cleaning and disinfecting.

The careful cleaning of lens cases is important for contact lens wearers. Wu and co-workers (2010a) found that digital rubbing of a lens case with rising with a MPS was effective at removing microbial contamination. Thereafter, the lens case should be allowed to air-dry and be stored face down between uses (Wu et al., 2010b). Many manufacturers further assist practitioners and patients by supplying a new contact lens case with each bottle of disinfecting solution.

Conclusion

With the growing popularity of daily disposable and extended-wear lenses, there has been a commensurate reduction in the use of contact lens solutions. Nevertheless, the majority of lenses prescribed still require lens care systems, and various options are available to satisfy the needs of patients. In the current climate of strict regulatory control in most markets, practitioners and patients can use these products with confidence. An important caveat is that patients use these lens care systems – as simple as they may appear – in precise accordance with the instructions supplied by the manufacturer. As discussed in Chapter 43, the prevalence of non-compliance with contact lens care systems is uncomfortably high, and practitioners are obliged to encourage patients constantly to use these systems as directed, in order to maximize their efficacy.

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Access the complete references list online at http://www.expertconsult.com.

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3

Rigid Contact Lenses

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11

Rigid Lens Materials

NATHAN EFRON

Introduction

It is interesting to speculate whether the present rigid lens materials would be invented and brought to market now if they did not already exist. Given the competitive situation that exists in relation to production costs and pricing policy, against the high background costs of product development in the biomedical field, the answer is probably no. They have, however, played an important role in the development of contact lens materials and occupy a small but significant place in the range of currently available products. Much of the relevant information is contained in the patent literature, which is analysed in some detail elsewhere (Kishi and Tighe, 1988; Künzler and McGee, 1995; Tighe, 1997).

POLYMETHYL METHACRYLATE

To appreciate the way in which rigid, as distinct from soft, materials have developed it is necessary to go back to the period following World War II. The new availability of plastics materials, specifically polymethyl methacrylate (commonly known as PMMA), led to the design and development of the first corneal lens as a replacement for glass corneo-scleral lenses. The PMMA lenses were prepared by polymerization of methyl methacrylate with a free-radical initiation system (Fig. 11.1) to form rods or buttons from which a lens was obtained by lathing and polishing. Fig. 11.1 represents the assembly of n methyl methacrylate units to form a PMMA chain n units long. PMMA was an ideal candidate for use as a hard contact lens material because it had similar appearance and ease of fabrication to glass, acceptable surface wettability and excellent durability. The lenses compared favourably with scleral lenses in that they were thin and lightweight, could be worn more comfortably and gave excellent visual correction.

THE NEED FOR OXYGEN

By the 1960s a greater appreciation of the effects of contact lens wear on the anterior eye was developing and the fact that PMMA is essentially a barrier to oxygen transport became widely recognized. Corneal physiologists at that time were not only able to carry out theoretical calculations on the effect of contact lenses on corneal respiration, but were also able to carry out well-differentiated experiments using PMMA and a very different material, silicone rubber (Fig. 11.2).

Some aspects of the structure and behaviour of polymers, including these two materials, have been outlined in Chapter 4. The most important property to consider in the context of the present discussion is the difference in their oxygen permeabilities. PMMA is a glassy thermoplastic material, which has advantageous optical clarity, processability and ease of sterilization, but the disadvantage, as a contact lens material, of virtual impermeability to oxygen. Silicone rubber, on the other hand, belongs to a group of materials known as synthetic elastomers, which are not only flexible but also show rubber-like behaviour (i.e. they are capable of being compressed or stretched and when the deforming force is removed they instantaneously return to their original shape). They consist of polymer chains that possess high mobility and are cross-linked at intervals along the polymer backbones. Because of this chain mobility, oxygen is able to diffuse rapidly through the structure. These polymers have oxygen permeabilities more than 100 times greater than that of PMMA. Silicone rubber is the most significant member of the group, with an oxygen permeability around 1000 times greater than that of PMMA. This extremely high oxygen permeability arises from the backbone of alternate silicone and oxygen atoms, which confers not only great freedom of rotation but also a much higher solubility for oxygen than is possessed by rubbery polymers with simple carbon backbones.

Silicone rubber lenses, surface treated to give acceptable wettability, were developed in the mid 1960s (McVannel et al., 1967) and found clinically to have little deleterious effect on corneal respiration (Hill and Schoessler, 1967). The problems of maintaining adequate surface properties, which were initially encountered in its routine clinical use, have never been fully overcome, however, and silicone rubber lenses are used only rarely. The uniquely high oxygen permeability of the silicon–oxygen backbone has, however, been harnessed in two distinct types of contact lens material: silicone hydrogels (Chapter 4) and the so-called rigid gas-permeable (RGP) materials described here. Because PMMA is now essentially redundant as a contact lens material, the term 'rigid gas-permeable' is equally redundant. All rigid lenses manufactured today (aside from PMMA) are gas permeable. For this reason, the term 'rigid lens' is used throughout this book, and is intended to refer to all rigid lenses apart from PMMA, unless the latter is specifically designated.

THE PROBLEM OF HYDROPHOBIC SURFACES

Elastomers, such as silicone rubber, are in many ways intermediate between thermoplastics such as PMMA and hydrogels such as poly(hydroxyethyl methacrylate) (polyHEMA). Thus, they possess to a degree the toughness associated with the former group of materials and the softness of the latter, and in this sense they are ideal candidates for contact lens usage. Unfortunately, however, they all possess the same inherent disadvantage: the molecular features required for true elastic behaviour invariably produce polymers with hydrophobic surfaces. All polymers in this group – not only the silicone-based materials – require some form of surface treatment to render them sufficiently hydrophilic for use as contact lenses, but because of the ease of chain rotation the surfaces slowly revert to their untreated

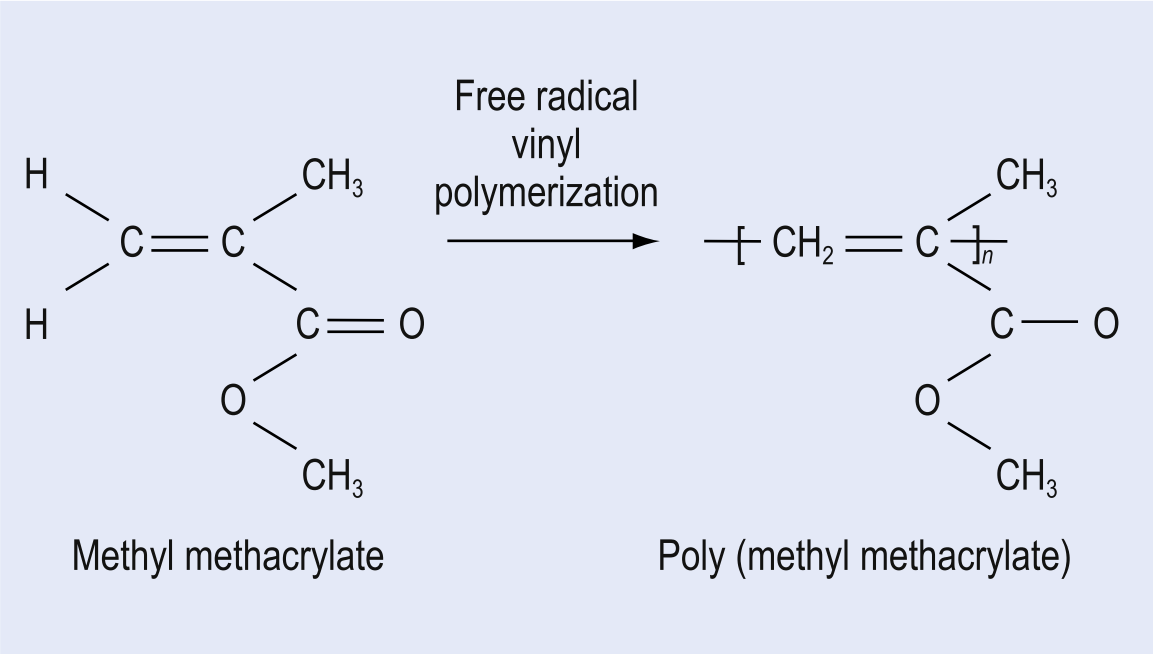

Fig. 11.1 Schematic representation of free radical polymerization of methyl methacrylate.

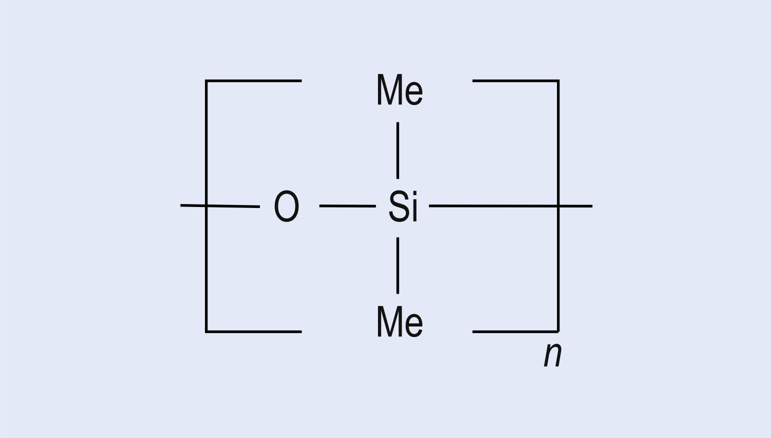

Fig. 11.2 Structure of silicone rubber. Me = CH_3.

state. This problem is made worse by the virtually instantaneous elastic recovery of the materials, which causes them to 'grab' the cornea after being deformed by the blink. This in turn displaces the posterior tear film and leads to lens binding. Despite the attempts to harness almost every available elastomeric material, as witnessed by the patent literature, no true elastomer has been successfully used as a commercial contact lens material.

THE SEARCH FOR BETTER MATERIALS

Once the need for a contact lens material with higher oxygen permeability than PMMA was established, a wide-ranging search began. There was, additionally, some belief that a more flexible material than PMMA would confer enhanced comfort. At first sight the task of finding an improved material would not seem too difficult as almost all thermoplastics are less rigid and more oxygen permeable than PMMA. Several flexible thermoplastics materials have been suggested as being suitable for contact lens manufacture in the patent literature, but none of these has achieved clinical significance. The most promising results were obtained with poly (4-methylpent-l-ene), a form of which is known commercially as TPX, and with cellulose esters such as cellulose acetate butyrate (CAB). TPX and CAB resemble each other in many ways. Both polymers are less rigid and less brittle than PMMA – they can conveniently be described as 'tougher'. The oxygen permeability of both materials is appreciably (of the order of 20 times) greater than that of PMMA (Kamath, 1969; Refojo et al., 1977) and both were capable of being fabricated by moulding techniques, which are inherently cheaper than lathe cutting, this still being the most widely used method of contact lens fabrication in the 1970s. Even the fact that TPX required a surface treatment step and that both materials (especially CAB) lacked the dimensional stability of PMMA did not seem to be inhibitors to their commercial future. The fact that they became, fairly quickly, curiosity materials was largely due to the appearance, and almost instant success, of the silicone acrylates.

Hybrid Rigid Gas-permeable Materials

The logic of silicone acrylate materials is inescapable. They combine, to a degree, the ease of preparation of PMMA and the oxygen permeability of silicone rubber. When the need to modify PMMA to improve its oxygen permeability arose, there was, therefore, no difficulty in recognizing that fact. The problem lay in combining such polymers to achieve a balance of properties. The origin of the problem is the fact that different types of reaction are used in the formation of the two materials. This can be illustrated by using the picture of polymers such as PMMA and hydrogels as 'washing line' polymers. The principle is that polymers of this type have a long backbone (i.e. the string or 'washing line') from which a variety of chemical groups may be suspended (the 'washing').

Other types of polymer, of which silicone rubber is one example, can be regarded as 'poppet bead' polymers. The individual units are joined just like the individual beads on a 'poppet bead' necklace. There is no 'washing' hanging from the chain and the properties of the polymer are controlled by the structure of the poppet beads themselves. The fundamental problem that prevented simple PMMA–silicone rubber combinations from being prepared is that the 'washing line' and 'poppet bead' chemistries are incompatible and beads cannot be inserted into the washing line. The requirement is that, in order to insert an individual monomer unit into an acrylate or methacrylate polymer such as PMMA, it is necessary that the monomer should have a carbon-to-carbon double bond (as shown in Fig. 11.1). Without the double bond the washing cannot be pegged onto the washing line. The siloxy-methacrylates that form the basis of current gas-permeable technology get round this problem in a well-recognized, but nevertheless quite ingenious, way. Short segments of the poppet bead chain are turned into 'washing' by attaching them to a chemical intermediate that contains the necessary double bond. This can be seen in the structure of the siloxy-methacrylate monomer (Fig. 11.3), which in essence consists of the individual units of silicone rubber structure pasted onto a modified methyl methacrylate molecule. On the basis of this simple picture, the story of gas-permeable lenses can be unfolded.

The Gaylord Patents – Harnessing Silicon

The major advance that enabled the development of rigid contact lens materials is found in the work of Norman Gaylord at Polycon Laboratories, described in a series of patents (Gaylord, 1974, 1978). There are two distinct aspects of this work that are worth noting. The first is the development of what has become the industry standard siloxy-methacrylate monomer, tris(trimethyl-siloxy)–methacryloxy-propylsilane (Fig. 11.3), commonly referred to as TRIS. The second is the recognition of the value of incorporating fluoroalkyl methacrylates (e.g. 1,1,9-trihydroperfluoro-nonyl methacrylate; Fig. 11.4), principally to enhance oxygen permeability. It is important to recognize that the bonds between individual carbon atoms are not disposed at right angles to each other and that molecules are not flat but rather have three-dimensional shapes. Although this point, which has been discussed in Chapter 4, is reflected in Fig. 11.1, it is impractical to do so in the representation of more complicated molecules such as the siloxy- and fluoromethacrylates

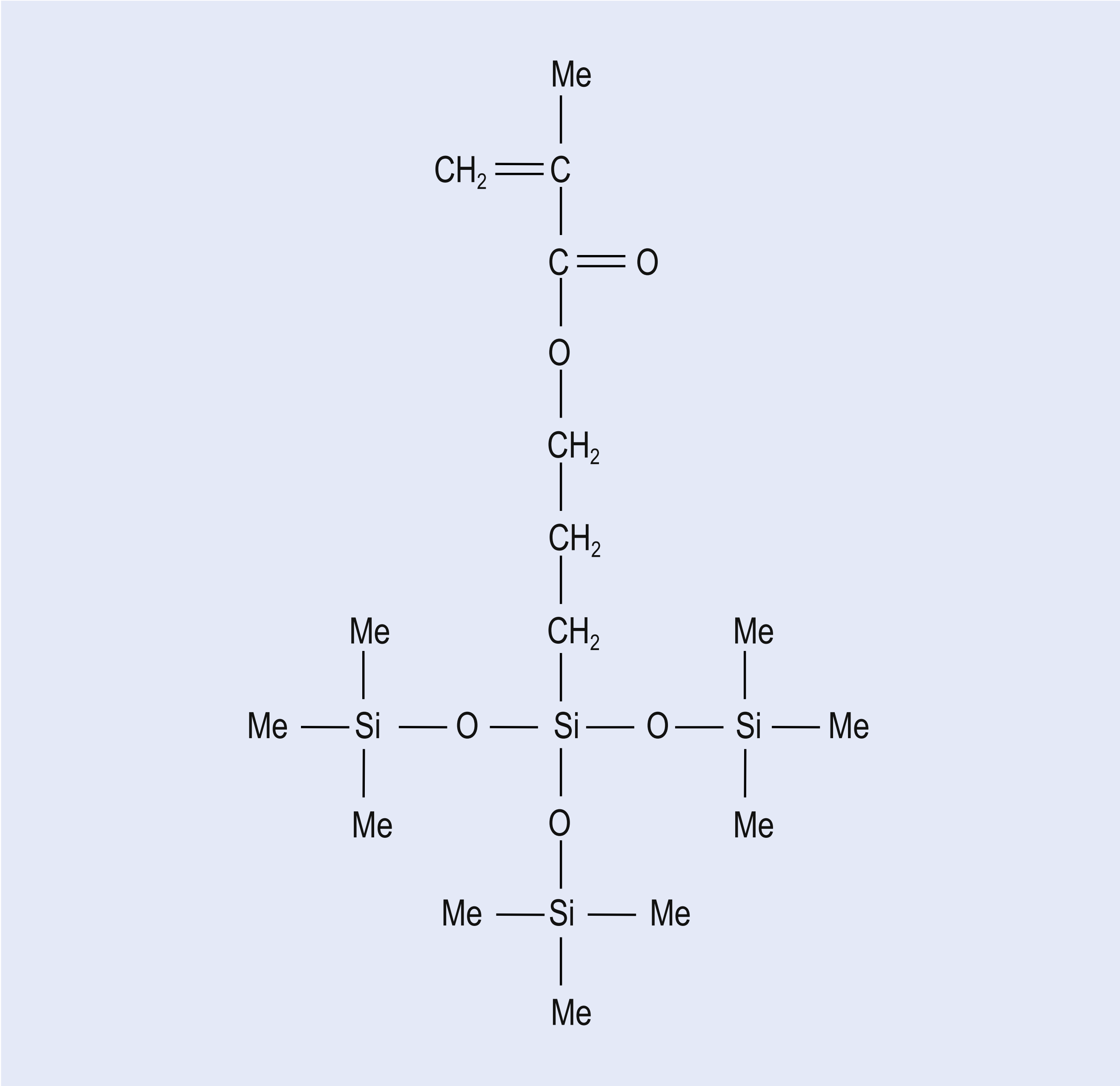

Fig. 11.3 Tris(trimethyl-siloxy)-methacryloxy-propylsilane (TRIS) monomer. Me = CH_3.

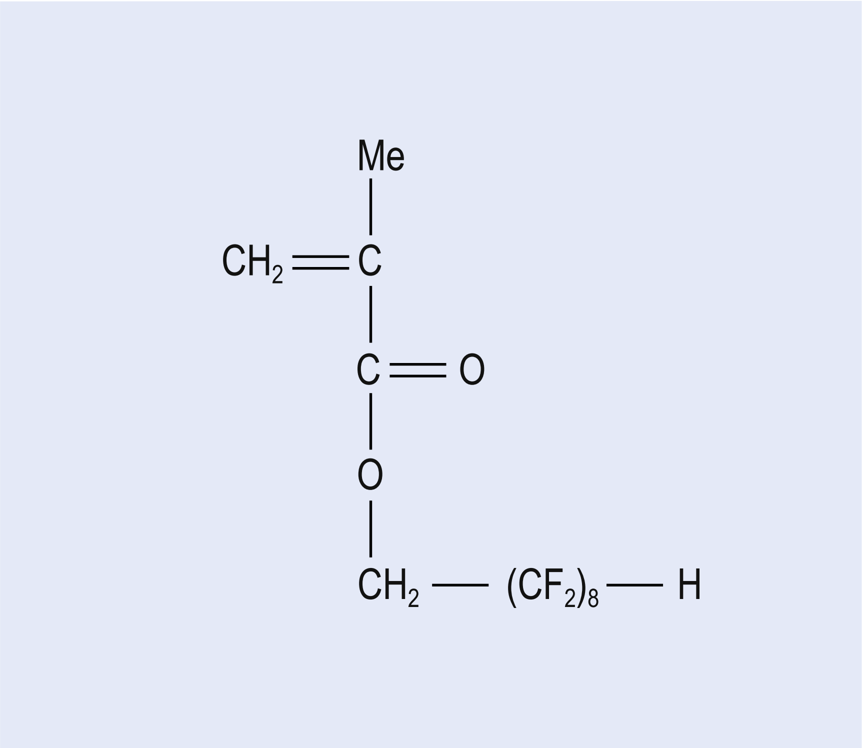

Fig. 11.4 1,1,9-trihydroperfluoro-nonyl methacrylate monomer. Me = CH_3.

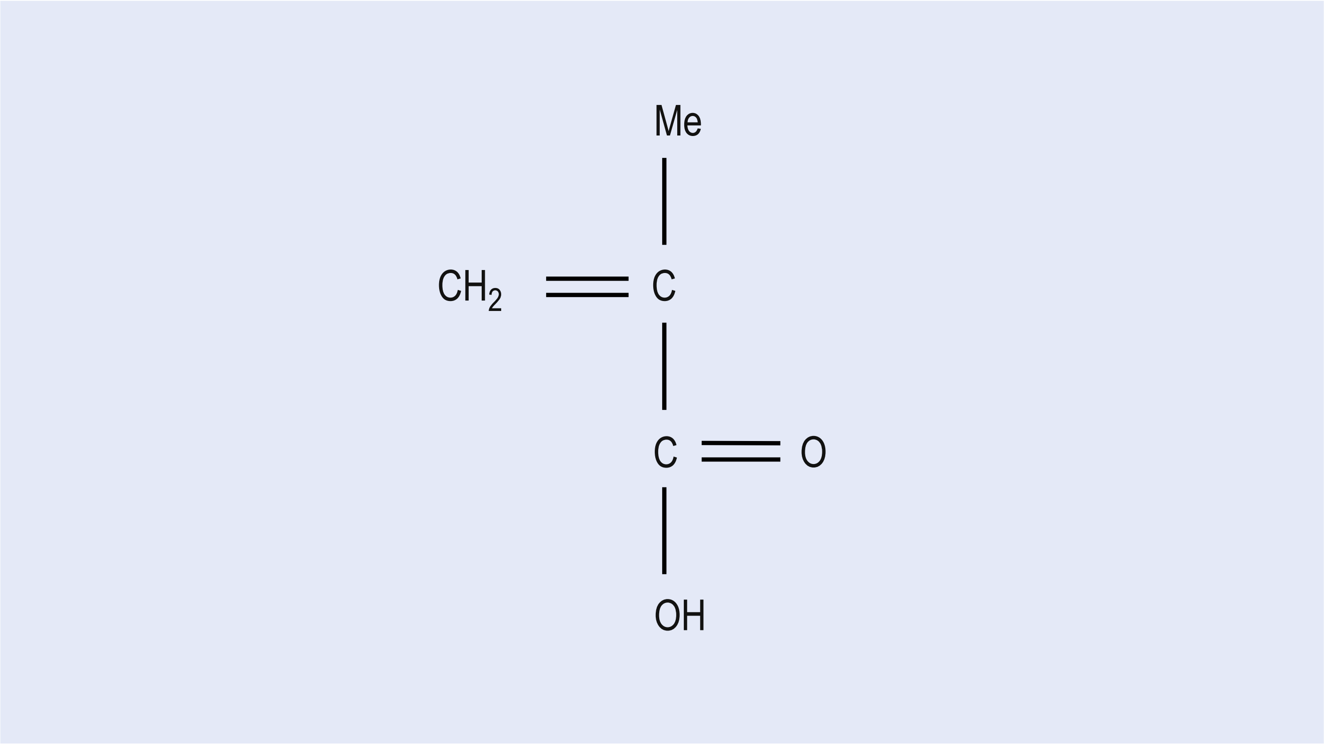

Fig. 11.5 Methacrylic acid monomer. Me = CH_3.

shown in Figs. 11.3 and 11.4. Both these aspects of the work of Gaylord have been subsequently developed, and together form the basis of most existing commercial rigid contact lens materials. Although TRIS is still the most widely used siloxy-methacrylate monomer in rigid lens manufacture, the fluoromethacrylate monomers employed in current commercial materials are much simpler than that initially used by Gaylord.

It is important to note that the concept of a fluorine-containing contact lens was not new. Fluorocarbons dissolve more oxygen than do hydrocarbons and give rise to polymers with somewhat higher oxygen permeabilities than their hydrocarbon equivalents. It was over 10 years after the first description of the advantages of contact lenses prepared from polymers derived from perfluoroalkylethyl methacrylates, in a series of DuPont patents, that significant commercial use was made of fluorocarbon-based contact lenses (Tighe, 1997). The reason is straightforward: there is a huge advantage in oxygen permeability of the siloxy-methacrylates over fluorocarbon methacrylates, which on their own do not produce a clinically significant balance of advantages over PMMA. The great advantage of the fluorinated methacrylates comes when they are used partially to replace methyl methacrylate in copolymers with TRIS. The balance of the three components (fluoromethacrylate, methyl methacrylate and TRIS) is adjusted to optimize oxygen permeability, hardness (which influences processability) and wettability. Although the Gaylord patents marked the beginning of the inventive thread, several other workers made significant contributions to the development of lenses with advantages in clinical practice by identifying ways of optimizing the balance of oxygen permeability, wettability and mechanical behaviour.

Within a 12-month period in 1978 and early 1979, at about the time of appearance of the third patent of Gaylord's, three workers began to file their separate series of patents related to siloxy-methacrylate-based contact lens materials. These were, in advancing order of the priority date for the first written filing, Kyoichi Tanaka (Toyo Contact Lens), Edward Ellis (Polymer Technology) and Nick Novicky, whose later patents (and presumably rights to the earlier patent) were assigned to Syntex (USA). The Ellis and Novicky patents form a clear line of continuation from the early work of Gaylord and, because of this, are best considered together (Ellis and Salamone, 1979; Novicky, 1980). The work of Tanaka – for which parallel filings exist in Japan and the USA – has some slight and significant differences mainly concerned with the inclusion of a hydroxyl group into the siloxy monomer to improve wettability (Tanaka et al., 1979). This was a significant early step in overcoming the technical obstacles to the development of silicone hydrogels, as separately discussed in Chapter 4.

The Ellis and Salamone patents used the basic concept of Gaylord with slight but significant modifications. The more important of these uses the basic composition – described by Gaylord – based on TRIS, but claiming novelty in the additional use of methacrylic acid (Fig. 11.5 – a hydrophilic monomer referred to but not exemplified by Gaylord) to improve surface wettability, and by the incorporation of an itaconate ester (e.g. dimethyl itaconate; Fig. 11.6). This composition formed the basis of the influential early range of Boston rigid lens materials.

The early Japanese patent of Tanaka marked the beginning of a rapid growth in Japanese patent activity, principally as a result of work assigned to Hoya Lens and Toyo Contact Lens. The subsequent clinical interest in the use of rigid lenses for extended wear in Japan stimulated particular interest in means of enhancing Dk. This interest was paralleled by a series of patents, which provide valuable information on the use of fluoroalkyl methacrylates in conjunction with siloxy-methacrylates, and the properties of fluoroalkyl methacrylates themselves. The properties,

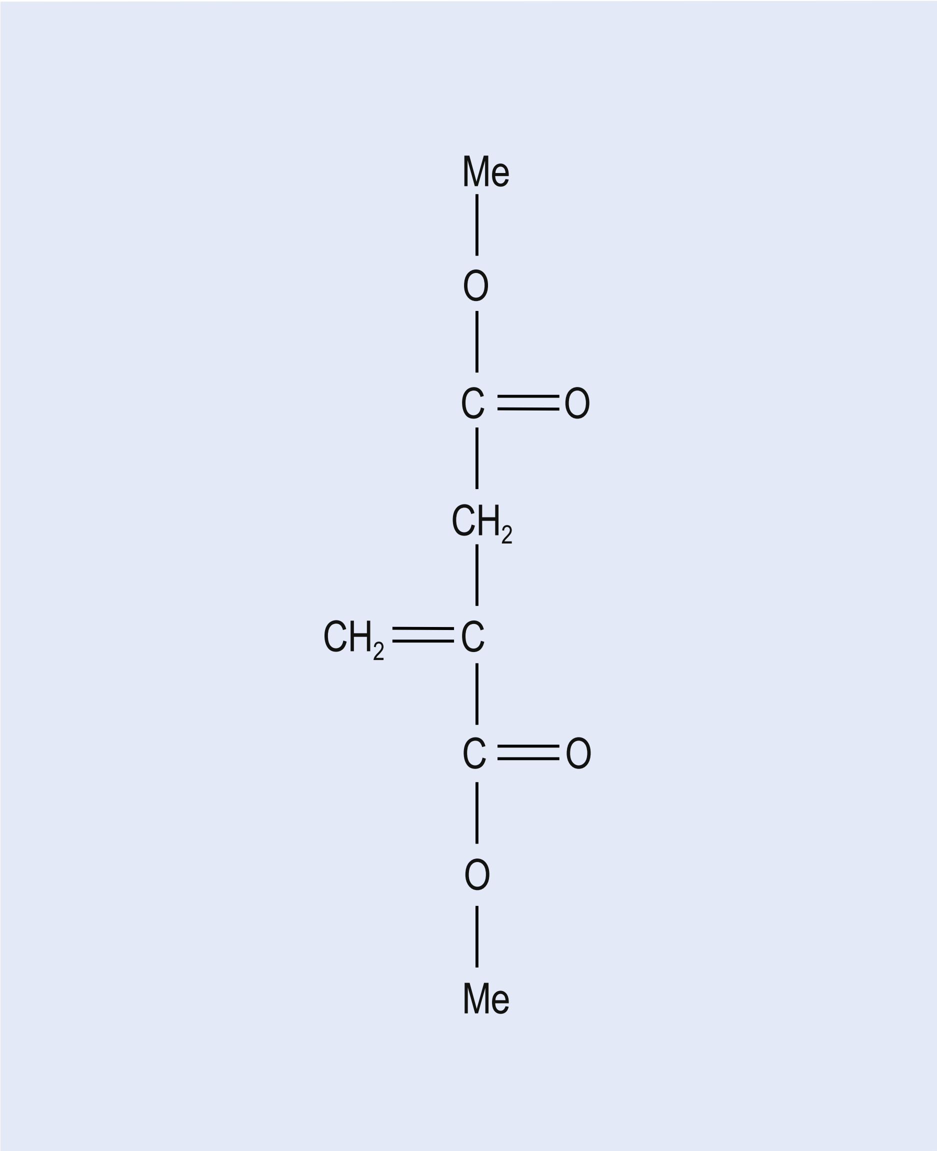

Fig. 11.6 Dimethyl itaconate monomer. Me = CH$_3$.

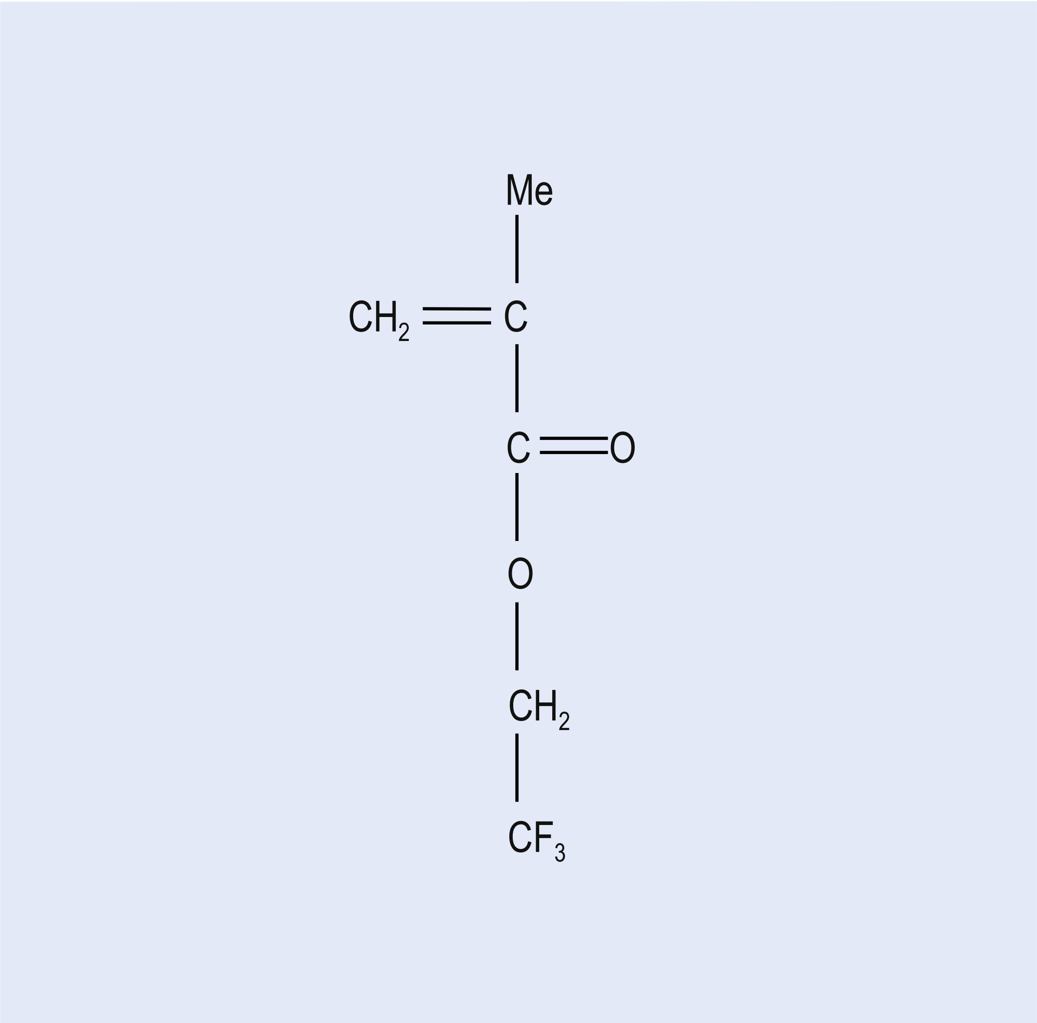

Fig. 11.7 Trifluoroethyl methacrylate monomer. Me = CH$_3$.

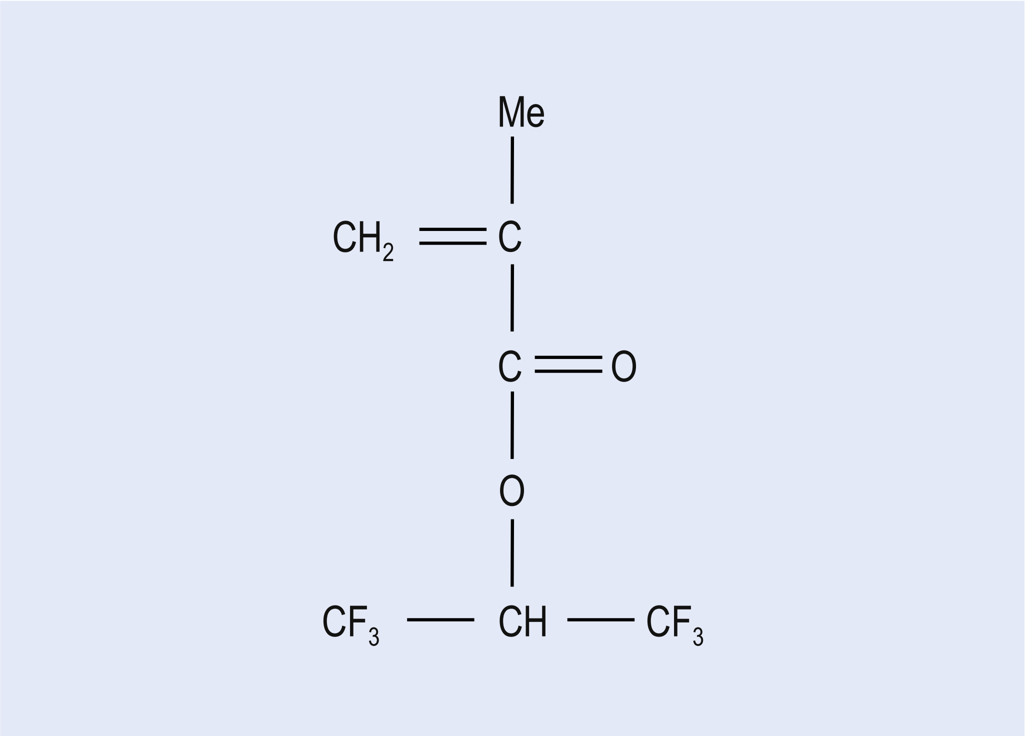

Fig. 11.8 Hexafluoroisopropyl methacrylate monomer. Me = CH$_3$.

specifically the permeabilities of the individual homopolymers, are carefully described. It is in the Japanese patent literature, for example, that the relative permeability along the series of homopolymers of methyl methacrylate, trifluoroethyl methacrylate (Fig. 11.7) and hexafluoroisopropyl methacrylate (Fig. 11.8), is disclosed (1 : 60 : 100). This indicates the relative advantage, in terms of permeability, of replacing methyl methacrylate by either of these two fluoro monomers. The ground is clearly seen in this patent for the development of fluorine-containing siloxymethacrylate gas-permeable materials (e.g. Equalens, Fluoroperm, Menicon SP) which penetrated the UK and US markets towards the mid 1980s. It is in the Japanese patents, however, that the relationship between composition and permeability of these materials is described (Tarumi and Komiya, 1982).

The readily discernible trend in the development of rigid contact lens materials described in the patent literature and discussed here is one of increasing oxygen permeability balanced against the retention of acceptable dimensional stability and ocular compatibility (characterized by wettability and deposit resistance). The essential structural developments have centred around four areas:

1. The TRIS component, characterized by attempts to incorporate higher proportions of more highly branched siloxy derivatives.
2. The use of fluorocarbon co-monomers in the place of hydrocarbon-based components such as methyl methacrylate.
3. The improvement of wettability by incorporation of hydrophilic co-monomers, or subsequent surface modification of the formed lens.
4. The development of cross-linking technology; rigid lens materials necessarily contain much higher levels of cross-linking agents than do soft lenses.

Much attention has been paid in the patent literature to the comprehensive coverage of all possible structural variants disclosed in the original patents won by Gaylord, published in 1974. Despite this, little that is truly new has appeared since then, and certainly nothing to match the leap forward brought by the identification of TRIS as a means of producing rigid contact lens materials with Dk values many times greater than PMMA. The process since that time has been one of refinement and improvement, based on the underlying principles that are contained in the patents described above.

One important refinement to increase both oxygen permeability and material strength was the introduction by Menicon of novel siloxanylstyrene monomers into the polymer backbone. Unlike its previous lenses (SFP and EX), which relied on silicone-containing methacrylate compounds for enhanced oxygen permeability, the Menicon Z material features tris (trimethylsiloxy) silyl styrene as the key monomer to fluoromethacrylate. This chemical structure results in excellent mechanical properties, allowing the lens to be significantly thinner than a typical rigid lens (Szczotka, 2004). It was the first rigid lens material classified in the 'hyperoxygen transmissibility' category with a Dk of 175, and is the only rigid lens that is approved by the US Food and Drug Administration for 30 days of continuous wear. This is a variation of the styrene–HEMA polymer used in the Softperm hybrid lens. The use of styrene adds a greater resistance to flexure and a lower specific gravity.

Plasma coating has been used to good effect in silicone hydrogel materials to overcome inherent hydrophobicity. The lenses are enclosed in an ionized gas with an equal number of positively and negatively charged species. The highly charged species within the gas plasma bombard the surface of the material, and the resulting energy causes a number of changes on the surface of the material. It is used in a wide variety of applications, including highly efficient surface cleaning, or increasing hydrophilicity and even hydrophobicity. A plasma oxidation surface treatment process has been developed for the treatment of rigid contact lenses produced from the Optimum range of materials (Contamac). The manufacturers claim the processes have been optimized to produce significant improvements in the wetting characteristics, without requiring a lengthy treatment procedure.

Silicone hydrogel polymers have been very successful in the form of soft lenses but can be made with a range of water contents from 0 to 60%. At low water contents (<10%), the polymers are rigid. There are two types of rigid silicone hydrogel materials. In one type, the water content and expansion are constrained by decreasing the ratio of hydrophilic monomers and increasing the cross-link density. Thus the polymer cannot absorb water into the interior of the matrix, but the surface can hydrate like a hydrogel lens. In the second type, a reactive hydrolysable monomer is included in the formulation. This means that, when the lens is placed in water, the reactive monomer hydrolyses, producing a hydrophilic surface like a hydrogel lens. The reaction cannot proceed into the interior as expansion is constrained by cross-linking. This type also has the novel property of regenerating the hydrophilic surface if the lens surface is damaged or the lens is repolished.

Commercial Rigid Materials and their Properties

Table 11.1 lists rigid contact lens materials that are commercially available at the time of writing. There has been some movement in recent years towards the standardization of experimental procedures for measuring material oxygen permeability (Dk). It is by no means certain, however, that all measurements quoted by manufacturers have been made to such standards. This is particularly true of the wide range of rigid lenses supplied, as they are from such a variety of sources. This fact presents a problem to the clinician in selecting materials on the basis of oxygen performance. Some cautionary comments are included here.

OXYGEN PERMEABILITY

Several different experimental procedures for determining oxygen permeability may be distinguished. In each case, oxygen at a known effective concentration passes from the donor side of the cell through the membrane (of known thickness and cross-sectional area) to a receiver side, also of known volume, where it is sensed. In the case of rigid polymers it is possible to use both gas-to-gas and liquid-to-liquid systems. This has the advantage that reference values for standard materials can be obtained in the gas-to-gas system, which does not suffer from some of the shortcomings of the liquid-to-liquid cell, in which the liquid is ideally stirred on both sides of the membrane.

The polarographic electrode technique, which is usually used for lens measurement, has several shortcomings. First, the cell is unstirred (thereby giving rise to boundary layer problems); secondly, the thickness of the contact lens normally shows a centre-to-edge variation (which produces uncertainties in the calculation); thirdly, because the lenses vary in curvature, the volume of the receiver side is not accurately fixed. In principle, this last point should be less important, because the technique is not usually operated in the manner that measures rate of increase in oxygen concentration of the receiver side of the cell, but rather the resultant equilibrium oxygen consumption by the electrode. The ability to do this relies on the assumption that oxygen transported to the receiver side is efficiently consumed by the electrode sensor and that, as a result, the partial pressure of oxygen on the receiver side is always effectively zero. With very permeable samples, however, these assumptions are not justified. In all cell configurations, it is important to have an oxygen-tight seal of the membrane separating donor and receiver chambers, but this again is difficult to achieve with the format and samples involved in contact lens measurement and edge-effect corrections must be made. A great deal of effort has gone into standardization of procedures and cross-correlation of results, but only when results have come from specialist laboratories can they be relied upon (Holden et al., 1990; Weissman and Fatt, 1991; Tranoudis and Efron, 1995; Benjamin and Cappelli, 2002).

Because in hydrogels, water is the oxygen transport medium through the lens, boundary layer effects are more readily analysed and eliminated. In rigid lenses, however, although measurements are easily made, the deviations from ideal behaviour increase with increasing permeability and are dependent upon the surface properties of the individual lens. It has been recognized for many years that, even in stirred cells, boundary layer effects produce greater problems with non-hydrophilic materials (Hwang et al., 1971). As a result of the various factors identified here, wide variations exist between reported Dk values for the same lens material. This is particularly problematical for the clinician, as there is no readily measured property (such as the water content of a hydrogel) that gives an independent guide to the permeability value. These issues have been discussed at length by Brennan et al. (1987).

MECHANICAL PROPERTIES

The problems associated with the use of increasing quantities of siloxy-methacrylates to achieve high oxygen permeabilities are twofold. First, incompatibility, phase separation and deterioration in mechanical properties – particularly dimensional stability – limit the proportion of such monomers that can be incorporated. Second, their use requires the incorporation of hydrophilic monomers containing hydroxyl, carboxyl, amide or lactam groups to improve wettability. These monomers tend to reduce oxygen permeability and produce low levels of water uptake that in turn reduce dimensional stability. It is well recognized that developments that have produced higher oxygen permeabilities have led to problems with mechanical properties, and that such problems are quite common. Despite this, the currently used mechanical property measurements, such as hardness, do not indicate any clear distinction between materials. Although materials are recognized to fail because of inadequate mechanical behaviour, there is certainly no accepted basis upon which the performance of lenses in a clinical setting can be correlated with presently used test measurements (Kerr and Dilly 1988; Jones et al., 1996).

Flexure

Lens flexure causes induced residual astigmatism on toric corneas. Silicone acrylate lenses have been shown to undergo significantly more flexure, and alter residual astigmatism more,

TABLE 11.1 Rigid Contact Lens Materials

Manufacturer	Trade Name	Colour	Material	Dk[1]
Bausch & Lomb	Boston II	Clear, blue, green	Silicone acrylate	12
	Boston IV	Clear, blue, electric blue	Silicone acrylate	19
	Boston Equalens[2]	Clear, blue, electric blue	Fluorosilicone acrylate	47[3]
	Boston ES[2]	Blue, ice blue, green, grey, brown, clear	Fluorosilicone acrylate	18
	Boston EO[2]	Blue, ice blue, green, grey, brown, ice green, electric blue	Fluorosilicone acrylate	58
	Boston Equalens II[2]	Clear, blue, green, red, yellow	Fluorosilicone acrylate	85[3]
	Boston XO[2]	Blue, ice blue, violet, green, red, yellow, clear	Fluorosilicone acrylate	100
	Boston XO2[2]	Visibility tint, blue, ice blue, violet, green, red, yellow	Fluorosilicone acrylate	141
Contamac US	Hybrid FS	Clear, blue, glacier blue, green, grey	Fluorosilicone acrylate	31
	Hybrid FS F/R Mould	Clear	Fluorosilicone acrylate	31
	Optimum Classic	Blue, glacier blue, green, grey	Fluorosilicone acrylate	26
	Optimum Comfort	Blue, brown, forest green, glacier blue, green, grey	Fluorosilicone acrylate	65
	Optimum Extra	Clear, blue, glacier blue, green, grey	Fluorosilicone acrylate	100
	Optimum Extreme	Blue, green, glacier blue, grey	Fluorosilicone acrylate	125
	Optimum GP System	Blue, green, glacier blue, grey	Fluorosilicone acrylate	26, 65, 100, 125
	Optimum HR 1.51	Blue	Fluorosilicone acrylate	50
	Optimum HR 1.53	Blue	Fluorosilicone acrylate	26
G.T. Laboratories	Fluorex 300[2]	Clear, blue, green, grey, aqua, rose brown	Fluorosilicate acrylic	30
	Fluorex 500[2]	Clear, blue, green, grey, aqua, rose brown	Fluorosilicate acrylic	50
	Fluorex 700[2]	Clear, blue, green, grey, aqua, rose brown	Fluorosilicate acrylic	70
InnoVision	Accu-Con	Clear, blue, green, grey, brown, dark blue	Fluorosilicone acrylate	25
	HydrO2	Soft blue, soft green, ocean blue	Fluorosilicone acrylate	50
Lagado Corporation	SA 18[2]	Clear, blue, grey, green, brown, dark blue, dark green	Silicone acrylate	18
	SA 32[2]	Clear, blue, grey, green, brown, dark blue, dark green	Silicone acrylate	32
	FLOSI[2]	Clear, blue, grey, green, brown, dark blue, dark green	Fluorosilicone acrylate	26
	ONSI-56[2]	Blue, green, grey, blue-violet, clear	Fluorosilicone acrylate	56
	TYRO-97[2]	Clear, blue, green, grey, blue-green	Fluorosilicone acrylate	97
The LifeStyle Company	SGP	Blue, green, brown, grey	Siloxane acrylate	22
	SGP II	Clear, blue, green, brown, grey	Siloxane acrylate	43.5
	SGP 3	Clear, blue, green	Fluorosiloxane acrylate	43.5
Menicon	Menicon Z[2]	Light blue and clear	Fluorosiloxanyl styrene	163[4]
Paragon Vision Sciences	Fluoroperm[2]	Clear, blue, green, grey, majestic blue, crystal blue	Fluorosilicone acrylate	30
	Fluoroperm 60[2]	Clear, blue, green, brown, crystal blue	Fluorosilicone acrylate	60[3]
	Fluoroperm 92[2]	Clear, blue, green	Fluorosilicone acrylate	92[3]
	Fluoroperm 151[2]	Blue, crystal blue	Fluorosilicone acrylate	151[3]
	Optacryl 60	Blue	Silicone acrylate	18
	Paragon HDS[2]	Forest green, emerald green, sapphire blue, crystal blue	Fluorosilicone acrylate	58[3]
	Paragon HDS NON-UV	Blue, green	Fluorosilicone acrylate	58
	Paragon HDS 100[1]	Blue, green	Fluorosilicone acrylate	100[3]
	Paragon HDS HI 1.54	Blue, green	Fluorosilicone acrylate	22
	Paraperm O2	Clear, blue, green, electric blue	Silicone acrylate	15.6
	Paraperm EW	Clear, blue, green	Silicone acrylate	56[3]
	Paragon THIN[2]	Blue, green	Fluorosilicone acrylate	29
Stellar	OP-2	Clear, blue, brown, grey, green	Fluorosilicone acrylate	15
	OP-3[2]	Clear, blue, brown, grey, green, dark blue, dark green	Fluorosilicone acrylate	30
	OP-6[2]	Clear, blue, brown, grey, green	Fluorosilicone acrylate	60

[1] ISO/Fatt method.
[2] UV absorber/inhibitors available.
[3] FDA approved for 7-day extended wear.
[4] Approved for 30-day extended wear

than do PMMA lenses at all centre thicknesses (Harris et al., 1982). For both lens types, lenses thinner than 0.15 mm flexed significantly more than thicker lenses. This critical centre thickness should be considered when fitting these lens types on toric corneas (Harris et al., 1987). However, it is not correct to assume that all gas-permeable lenses flex more than PMMA. Lin and Snyder (1999) compared flexure in low-(15), medium-(60) and high-(150)Dk materials, as measured by keratometry over the lenses. No significant differences were found within or between lens materials when comparing magnitude of flexure. The flexure of both PMMA and Boston XO materials were investigated by Collins et al. (2001) in three centre thicknesses (0.05, 0.10

and 0.15 mm) using a videokeratoscope; they also found no significant differences in flexure. Methods of flexure measurement are discussed in Chapter 14.

Hardness

Little work is carried out on the measurement of clinically relevant mechanical properties, and the values quoted are almost invariably related to the hardness of the material. Although hardness tests have some place in contact lens characterization, they do not reflect the type of mechanical failure or problems that normally arise, which are usually associated with fracture, chipping or splitting, or distortion. In the absence of agreed standards for suitable methods, manufacturers' quoted data are usually obtained with one or other of the standard hardness test methods.

Hardness can be defined as resistance to penetration. In a hardness test, an indenter is pressed on the surface of the material under test, and the extent to which it sinks into the material for a given pressure and time is an inverse measure of the hardness. There are many hardness testers available commercially that are suitable for plastics and rubbers, including the Vickers indenter, the Rockwell hardness tester and the Shore durometers. These may be divided into three categories:

1. Hardness tests that measure the resistance of a material to indentation by an indenting probe (e.g. Brinell, Vickers and Shore durometers): some tests measure the indentation with the load applied and some measure the residual indentation after the load is removed.
2. Hardness tests that measure the resistance of a material to scratching by another material (e.g. the Bierbaum scratch test, the Moh hardness test): similar techniques are commonly used in paint testing and involve pulling the sample beneath a loaded indenter.
3. Hardness tests that measure recovery efficiency or resilience (e.g. the various Rockwell testers).

There is no common method of measurement in these tests. For example, the Rockwell A-scale hardness test measures the depth of penetration with the load applied, whereas the Rockwell R-, L-, M- and E-scale tests measure depth caused by a spherical indenter after most of the load has been removed. In these methods the amount of rebound or recoverable deformation is important. The Vickers Microhardness test differs again, in that a microscope is used to measure the diagonals of the pits left by a diamond-shaped indenter on a square base. There is a linear relationship between the depth of impression and the hardness number. Each of the hardness methods uses an arbitrary scale and, although the scales can be approximately compared, precise correlation is not possible.

The extent of scratching of rigid contact lens materials was evaluated by Tranoudis and Efron (1996) and this property was related to material oxygen permeability and refractive index. One hundred and forty lenses made from 28 different rigid materials were evaluated in a masked and randomized manner. Scratches were created on the front surface of the lenses using an apparatus that was specifically designed and constructed for this experiment. The extent of scratching was quantitatively evaluated using a computer-based scanning and image analysis system. The oxygen permeability of all materials was measured using the polarographic method. An Atago N3000 hand-held refractometer was used to measure the refractive index of these materials. Three significant correlations were revealed: an inverse relationship ($r = -0.813$, $P < 0.0001$) between the oxygen permeability and the refractive index, a positive relationship ($r = 0.511$, $P < 0.008$) between oxygen permeability and the extent of scratching, and an inverse relationship ($r = -0.539$, $P < 0.0058$) between the refractive index and the extent of scratching.

SURFACE PROPERTIES

Similar problems arise with the measurement of wettability by contact angle techniques. In this case, the effect of soaking on water uptake and thus the wettability of materials, coupled with the use of the inverted or captive air bubble technique in solutions other than water, combine to produce wide variations, because of the different methodologies, in the reported values for a given material. The field of contact lens surface properties has also become more complex with the passage of time. The water wettability of materials provides a good primary indication of the ability of tears to form a coherent and stable layer on the surface of the material. It tells nothing of the compatibility of the material with tears.

Unfortunately, the inverted (captive) air bubble technique has been identified as a standard in contact lens work. The measurement is made after an air bubble is allowed to impinge, from underneath, onto the surface of the sample, which is suspended in an aqueous liquid. This is the most difficult type of contact angle to measure correctly as it involves judging where the base of a distorted sphere just impinges on a surface. More importantly, the air bubble has to displace water from the surface of the sample, which is frequently presoaked. As all the siloxy-methacrylate materials contain appreciable amounts of hydrophilic monomer to improve surface wettability, they all retain a strongly adsorbed water layer at the surface under these conditions. Not surprisingly, therefore, with this method very similar and very low so-called wetting angles are obtained with current rigid lens materials. What is measured in each case is the value for a diffuse layer of water on a polymer surface. The values are similar to those obtained by this technique with hydrogels. The biological and biochemical surface events, on the other hand, occur at a molecular level and do not recognize the diffuse water layer barrier that is sensed by macroscopic droplet techniques. This is the underlying reason for the lack of relevance to clinical practice of the wetting angle, as presently measured.

Well-established techniques exist which enable the wetting hysteresis and the detailed surface energy components, rather than a single wetting angle, to be determined. Biomaterials science makes widespread use of such methods; the contact lens community could profitably do the same.

OPTICAL PROPERTIES

Domínguez-Vicent et al. (2016) assessed the optical quality of four Boston contact lens materials with an optical device based on Schlieren interferometry. Specifically, they measured higher-order aberrations and their corresponding root mean square values of four different rigid gas-permeable contact lenses made from four different Boston materials: EO, ES, XO and XO2. For each lens, 30 measurements were performed with two optical apertures: 3.0 mm and 6.0 mm.

The root mean square error of higher-order aberrations was found to vary significantly with material type for both optical apertures ($p < 0.01$). The largest difference was obtained between the Boston EO and the Boston ES materials (for a 6.0 mm aperture), the mean difference being $(8.3 \pm 0.2) \times 10^{-2}$ µm. The modulation transfer functions, point spread functions and Strehl ratio values were similar among all Boston materials at the smaller optical aperture; however, differences between each material were more apparent for the 6.0 mm aperture, with the Boston ES material exhibiting the best optical quality.

REFRACTIVE INDEX

Fluorosilicone acrylate lenses are likely to have a refractive index between 1.420 and 1.460, whereas an index of 1.460 or greater usually indicates a silicone acrylate material. The refractive index of PMMA is 1.49. Unlike in spectacle lens dispensing, refractive index has rarely been a factor in the choice of rigid lens material. However, manufacturers are starting to introduce lenses with higher refractive indices. Contamac's Optimum HR material and Paragon Vision Sciences' Paragon HDS HI material have refractive index values ranging from 1.51 to 1.54. A benefit of these higher-index materials is the enhanced refractive effect the materials might have when used in aspheric multifocal designs. With the same amount of asphericity, a higher-index material will produce an increased add effect (Pence, 2009).

Conclusion

This chapter provided an outline of the basic chemistry of rigid plastics used in the contact lens industry, and has traced the successive developments in rigid lens materials primarily with reference to the patent literature. All stages of development have been driven by a parallel growth of information relating to the biocompatibility (the need for oxygen permeability and surface wettability) and the clinical performance of the lenses.

Predicting compatibility in vivo from tests in vitro is never entirely successful. Increasingly, however, it enables differences between the performance of materials to be successfully predicted. In addition the use of biological probes, such as animal cells, and interaction with biological sera, provide useful information in the development of new biomaterials. The area is complex, but offers several approaches that will improve considerably on current techniques, and will have some relevance to the clinical performance of rigid contact lenses.

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Access the complete references list online at http://www.expertconsult.com.

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12

Rigid Lens Manufacture

NATHAN EFRON

Introduction

Although lathing technology has been used to fabricate contact lenses since their invention over 130 years ago, developments over the past quarter of a century in precision engineering, materials technology and computer control systems have resulted in a capability to manufacture lenses of almost any imaginable shape – from basic spherical lens forms to highly complex aspheric designs. These developments have resulted in renewed interest in rigid lenses, and in particular miniscleral lenses, which despite representing a small minority of lenses sold are still a very important alternative form of vision correction – and indeed the only form of contact lens that will provide adequate vision in cases of corneal distortion (as occurs in keratoconus). The type of use or design of rigid lenses prescribed has shifted substantially over time. In 1996, 80% of rigid lenses were of spherical design (Morgan and Efron, 2008); this had dropped to 44% in 2015 (Morgan et al., 2016). The proportion of lenses requiring more specialized manufacturing techniques has risen accordingly, as is evident from worldwide rigid lens prescribing data for 2015 (Morgan et al., 2016) (Fig. 12.1).

This chapter will explain the process of rigid lens manufacture and presents an analysis of the impact of regulatory constraints on the rigid lens sector.

Rigid Lens Manufacture

The process of lathe cutting soft lenses has already been outlined in Chapter 5. Here, a more comprehensive illustrative account of the process of lathe cutting will be presented in the context of rigid lens manufacture.

RAW MATERIALS

The raw material is supplied to the lens manufacturer in the form of flat cylindrical buttons of 12.7 mm diameter and circa 4.3 mm thickness. Some types are sold with a concave depression in one surface as preparation for base curve cutting. These are supplied in various colours and the tradename of the product is typically imprinted on one surface of the button (Fig. 12.2). The choice of material is largely dictated by clinical needs, with oxygen permeability being a key consideration. The latest range of rigid materials is designed as 'super' gas permeable with Dk values of over 150 Barrers. These materials typically require some postproduction surface treatment in order to ensure a wettable surface. Manufacturers often seek extended-wear approvals for lenses made from these polymers, for use in overnight orthokeratology. From the standpoint of the manufacturing laboratory, however, consideration needs to be given to the 'machinability' of the material, as some materials are more susceptible to surface deterioration and degradation of optical quality compared with other materials when subjected to the same manufacturing processes (Meyers, 1997). Manufacturing laboratories that wish to make lenses from the latest rigid materials need to use only the best types of lathes available. Typically these lathes will use hydrostatic X,Y slides and air-bearing spindles, all under sophisticated computer control.

GENERATING THE LENS BACK SURFACE

Some lathes are configured so that they can be used to generate both the front and back surface of the lens; however, in practice, separate lathes are used in order to optimize the lens production process. Fig. 12.3A shows a lathe configured for generating the lens back surface.

The button is first secured in a carrier, or dolly, which is a small hollow cylinder lined with plastic (Fig. 12.3B). This assembly is secured to a back surface lathe in a clamp, or collet (Fig. 12.3C) and this assembly is set spinning at a high rate about its central axis. Orssengo et al. (1997a) have demonstrated that the accuracy in achieving the desired back optic zone radius can be increased by minimizing the pressure applied to the button when fixing it into the collet of the lathe.

A 'rough' or preparation diamond-tipped tool is automatically advanced towards the spinning button and the posterior surface lens shape is cut by advancing the diamond cutter from the edge to the centre of the button (because the button is spinning around its central axis, a cut on only one side of the button will result in the full width of the button being cut) (Fig. 12.3D). The waste plastic that is lathed away (swarf) is extracted via an air vacuum tube mounted above the lathe assembly. Some laboratories will strive to improve swarf and surface management by the use of suitable cutting fluids. These cutting fluids or sprays maintain a cooler surface and assist the swarf to peel away cleanly from the button surface. Any clogging of swarf around the diamond tool will very quickly result in a pitted and overheated surface. A fine diamond tool is used to make the final surface cut so as to render a smooth, high-quality finish. With some lathes, the fine cut can be so precise as to obviate the need for polishing. This can be achieved with the use of gem-quality diamond tools, air-bearing spindles and slides and nanometer surface control. The best of these lathes can achieve a surface roughness (R_a) close to 3–8 nm.

A diamond tool advances from the side to reduce the button diameter to the required size of the finished lens. The button is released from the lathe and the cut surface is given a brief polish – typically for about 5–30 seconds, depending on the lathe/material combination (Fig. 12.3E). The thickness of the button is measured at its thinnest point (centrally) and this information is programmed into the front surface lathe so that the final lens will be cut to the desired thickness.

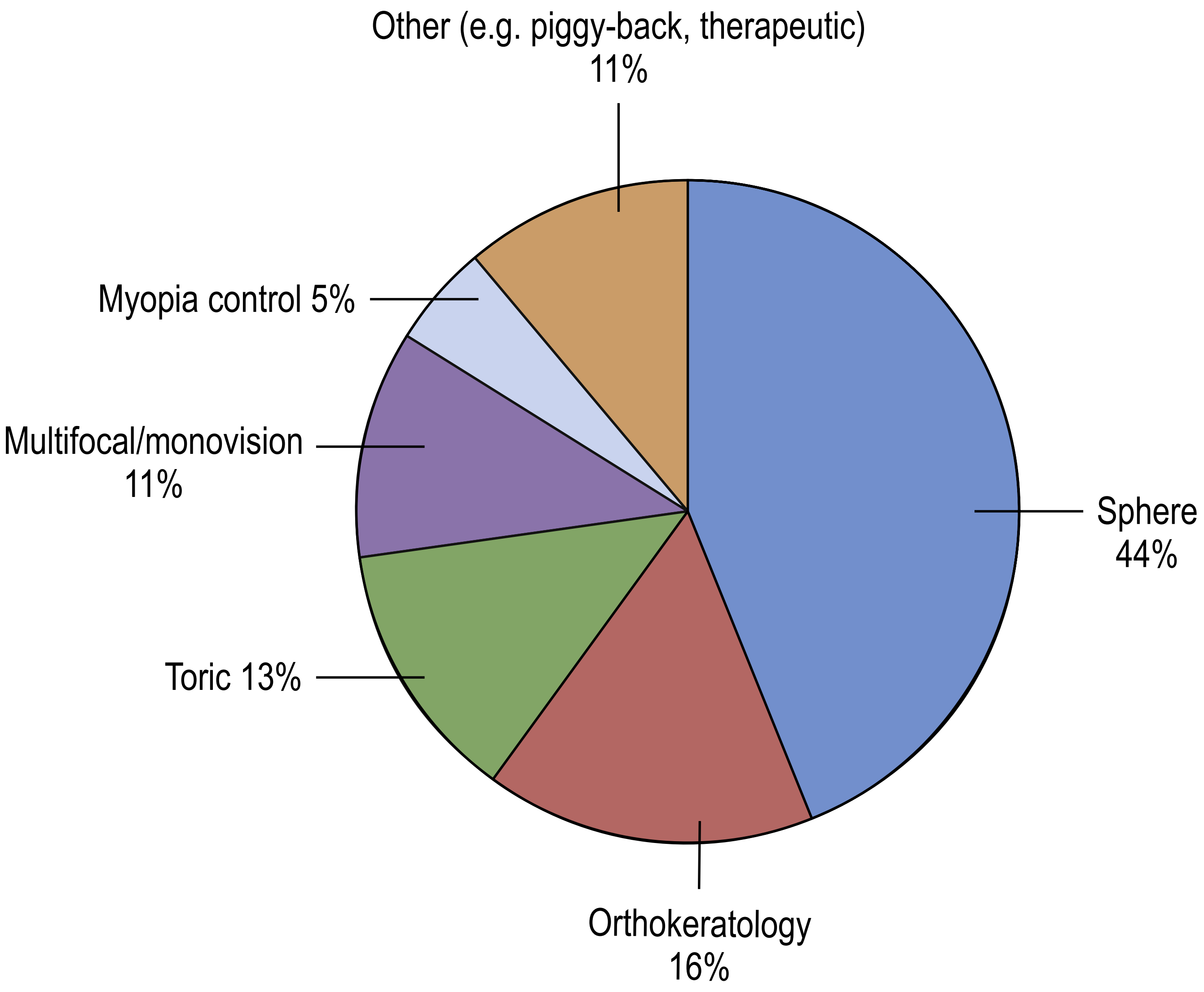

Fig. 12.1 Rigid lens prescribing. (After Morgan et al., 2016.)

Polymer Technology
BOSTON
XO

Fig. 12.2 Rigid lens buttons. (Courtesy of Polymer Technology Boston XO.)

In the process of lathing and polishing, care must be taken to avoid overheating the lens material, because the generation of excess heat can result in warpage, surface crazing (Sanford, 1987) (Fig. 12.4) and errors in generating the desired surface curvature (Orssengo et al., 1997b).

Strategies employed to avoid this problem include programming the lathe to make incremental cuts rather than one continuous cutting action, and passing a constant flow of air / cutting fluid over the lathing assembly to keep it cool.

GENERATING THE LENS FRONT SURFACE

In order to generate the lens front surface, the button needs to be fixed onto a mount, or arbour (which will later be secured to a front surface lathe). This process of mounting the button onto the arbour is known as blocking. The arbour can be a metal or plastic cylindrical tool, one end of which is dome shaped so that the curve of the dome approximately matches the form of the posterior lens surface that has previously been generated. The operator heats the arbour to approximately 80°C and applies low-melting-point wax to the dome end or, in the case of a plastic tool, applies a UV-sensitive glue that can be cure to a hard form after centering. The newly cut back surface of the button is mounted on to the wax-surfaced dome of the arbour and carefully centred (Fig. 12.5A) via either a centrifugal means or by some form of precision alignment jig.

The arbour–button assembly is clamped into a front surface lathe (Fig. 12.5B) and the button is inspected under magnification while spinning at low speed to confirm that it is properly centred; if this were not the case, the front and back surfaces would not be co-concentric, and both prism power and uneven edge thicknesses would inadvertently be introduced into the lens. Once centration is confirmed, the thickness of the button is determined by a computer-controlled thickness gauge. A series of incremental cuts is made from the edge to the centre with a rough preparation diamond-tipped cutter, then with a fine diamond-tipped cutter, in precisely the same manner as for the back surface (Fig. 12.5C). As front surface cutting requires that the spindle spins in the opposite direction of back surface face cutting, however, the diamond holders are mounted on the front surface lathe in different configurations to the back. This specific configuration allows for optimal swarf and surface management. The front surface is cut to a depth that will result in a finished lens of desired thickness. The arbour–button assembly is released from the lathe and mounted in a support in a polishing machine. The front surface is polished for about 30 seconds to 2 minutes with a soft pad impregnated with a water-based polishing compound (Fig. 12.5D).

ENGRAVING, MARKING AND FENESTRATION

At this juncture in the manufacturing process – with the near-finished lens still mounted on the arbour (Fig. 12.6A) – the lens can be engraved or marked. Engraving can be undertaken using a pantographic device, whereby the operator traces the desired letters to be engraved on the lens against a stainless-steel master template into which the letter forms are impressed; such a device is illustrated in Fig. 12.6B. Typical engravings might include 'R' and 'L' to indicate the right and left eyes, the back optic zone radius, total lens diameter or a lens identification code.

If requested by a practitioner, fenestrations (small holes) can be introduced into the lens using a laser (Fig. 12.6C). This procedure is usually done to the finished lens. Both lens surfaces are given a light manual polish following these procedures.

EDGE POLISHING AND FINAL INSPECTION

The lens is released by either ultrasonic or manual means from the arbour and washed in detergent to remove any excess wax remaining on the lens surface. Edge polishing can be carried out using a polishing machine such as that illustrated in Fig. 12.7A. (With certain lens designs and lathes, the lens edge can be finished with a smooth, fine cut so that polishing is not required.) The lenses are fixed to a support arm by placing the lens front surface onto a concave rubber cup support, through which air is drawn to 'suck' the lens firmly in place. The spindle rotates around its long axis, and the spinning lens is lowered onto a flat rotating polishing pad and moved slowly from side to side. By doing this, the polishing pad alternately brushes towards the anterior and posterior edges, creating a smooth, rounded edge.

After polishing, the lens is supported in a small suction holder and the edges are inspected using a 10× hand magnifier

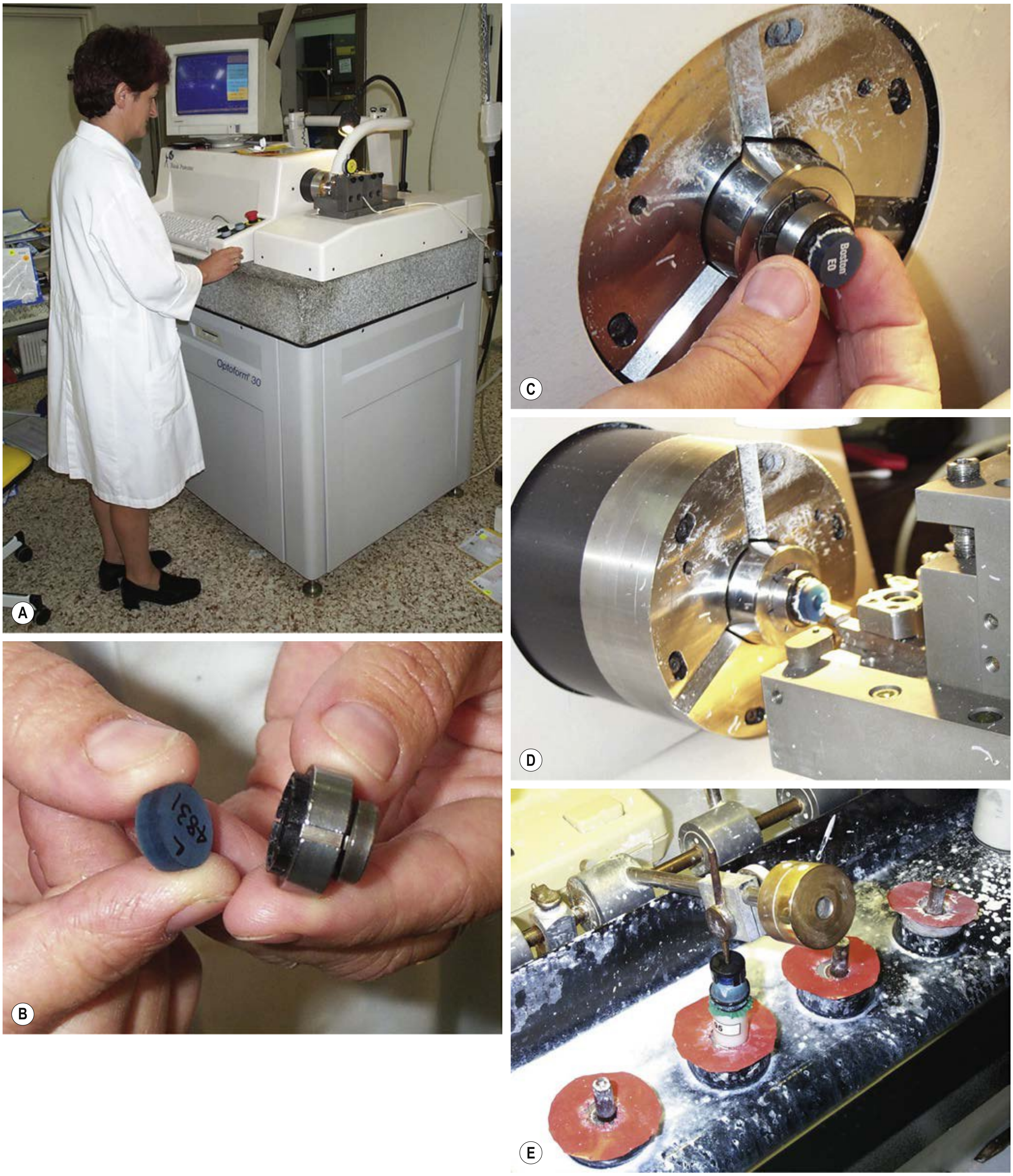

Fig. 12.3 Generating the rigid lens back surface. (A) Back surface lathe. (B) Button about to be mounted in dolly. (C) Button–dolly assembly is collected in lathe. (D) Back surface curve being cut into the button with a diamond-tipped tool. (E) Back surface polishing. (Courtesy of Sterling Ultra Precision.)

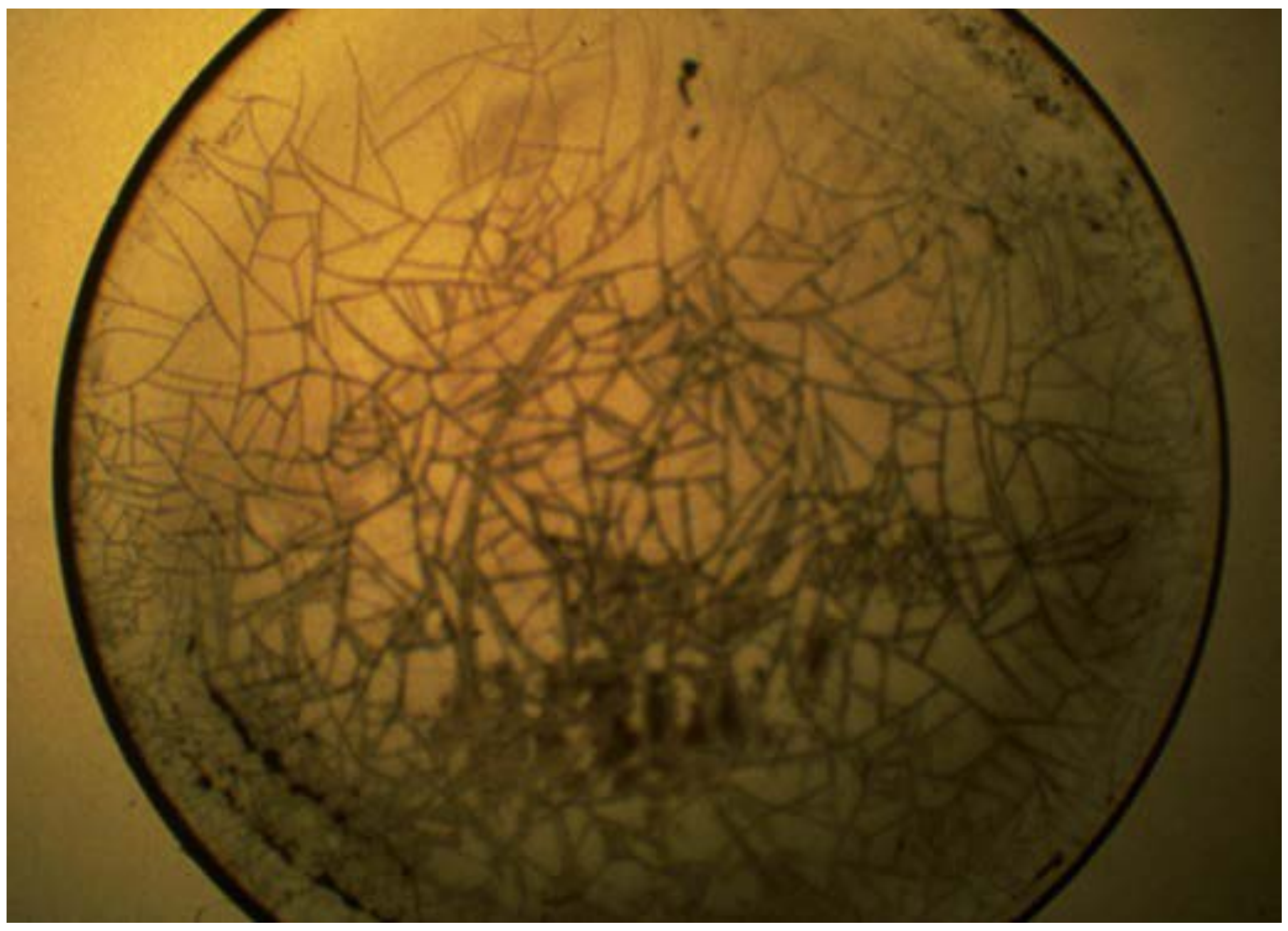

Fig. 12.4 Crazing and cracking appearing in a rigid lens that has been improperly manufactured; this could be due to overheating during lathing or use of an inappropriate solvent.

(Fig. 12.7B). Any irregularities can be rectified manually by polishing the lens – again supported in a suction holder – against a small rotating polishing pad (Fig. 12.7C). Ehrmann et al. (1999) have described an optical profilometer that can accurately portray the edge profile of rigid lenses; such a system may pave the way to a more exact approach to the edge finishing of rigid lenses in the future. Modern digital optical inspection devices can also provide a highly accurate and detailed image of the lens edge and surface.

The key parameters of the lens – power, back optic zone radius, total diameter, optic zone diameter and thickness – are checked (see Chapter 14), to ensure that these fall within expected tolerances (see Appendix B). If all is well, the lens is cleaned and dispatched to the customer. Proctor (1997) advises that rigid lenses should be soaked for 24 hours prior to checking the lens parameters because certain lens forms may display a small amount of flattening upon hydration (Proctor and Efron, 1997).

Lenses may be dispatched in solution or dry. If supplied dry, the practitioner should soak the lenses for at least 4 hours before

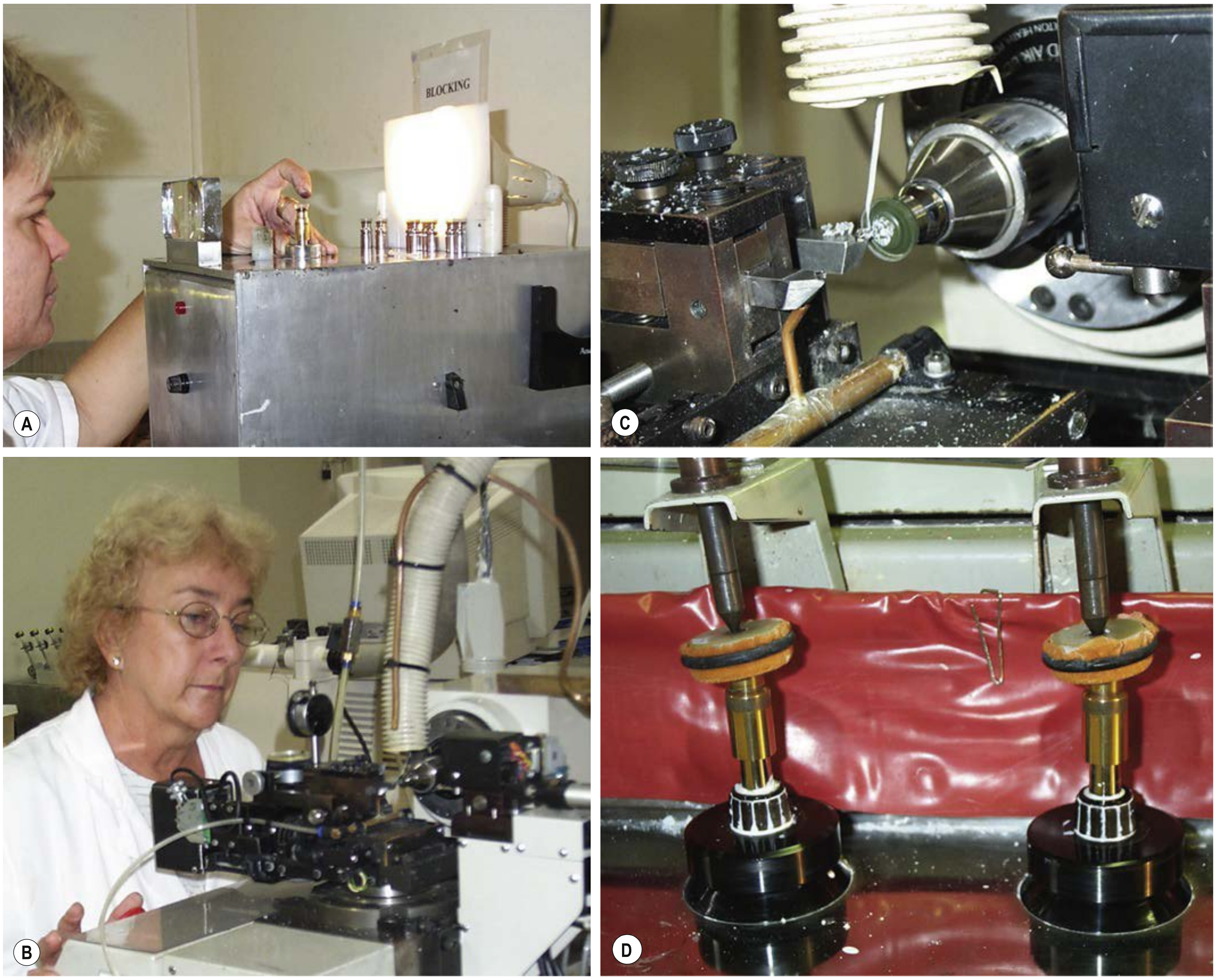

Fig. 12.5 Generating the rigid lens front surface. (A) Blocking the button on to a brass arbour. (B) Front surface lathe. (C) Front surface curve being cut into the button with a diamond-tipped knife. (D) Front surface polishing.

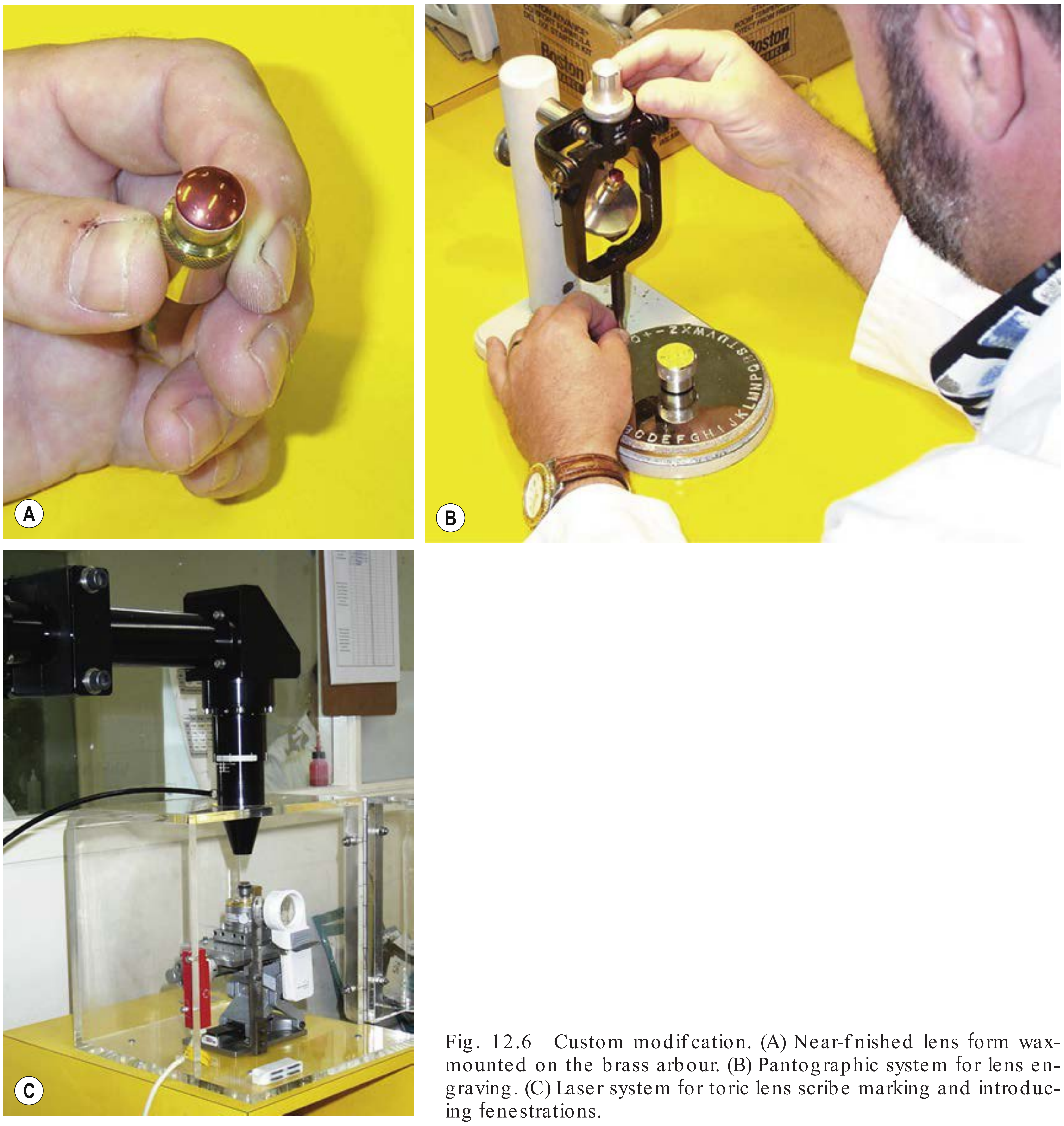

Fig. 12.6 Custom modification. (A) Near-finished lens form wax-mounted on the brass arbour. (B) Pantographic system for lens engraving. (C) Laser system for toric lens scribe marking and introducing fenestrations.

dispensing them to the patient, to ensure optimal lens surface wettability.

Merindano et al. (1998) used the techniques of interferential shifting-phase microscopy and scanning electron microscopy to examine the surfaces of unworn rigid lenses manufactured using lathe cutting. They found a higher degree of surface irregularities in lenses made from materials of higher oxygen permeability. These results may give insights into factors such as surface wettability and propensity for deposit formation, but are unrelated to lens comfort as the irregularities were measured on a nanometre scale and therefore could not be detected by the human cornea.

Specialty Rigid Lens Manufacture

Computer numerically controlled lathes have ushered in a new era in which virtually any curve a practitioner wants can be cut. The lathes are controlled from a centre point to achieve the desired rate of change from centre to edge. They have also reduced the need for excessive polishing. This helps to ensure that the lenses produced are consistent and easily duplicated. From the desired base curve, the computer mathematically calculates the spline curve, which starts at the optical zone and ends at the tip of the lens.

TORIC RIGID LENS MANUFACTURE

Either surface of a rigid lens will sometimes require a toric form for the correction of astigmatism and/or to achieve rotational stabilization. This can be achieved by directly lathing a toric surface on to the button, or by a technique known as crimping. The process of directly lathing a toric back surface on to the lens button is achieved by using a fly-cutter, which is a diamond tool that has its cutting tip set at right angles to the axis of its support shank. The positions of the fly-cutter and lens blank are reversed, so that the lathe manoeuvres the lens button in an arc around the fly-cutter, which spins in a fixed position. A similar principle is applied for generating a front toric surface.

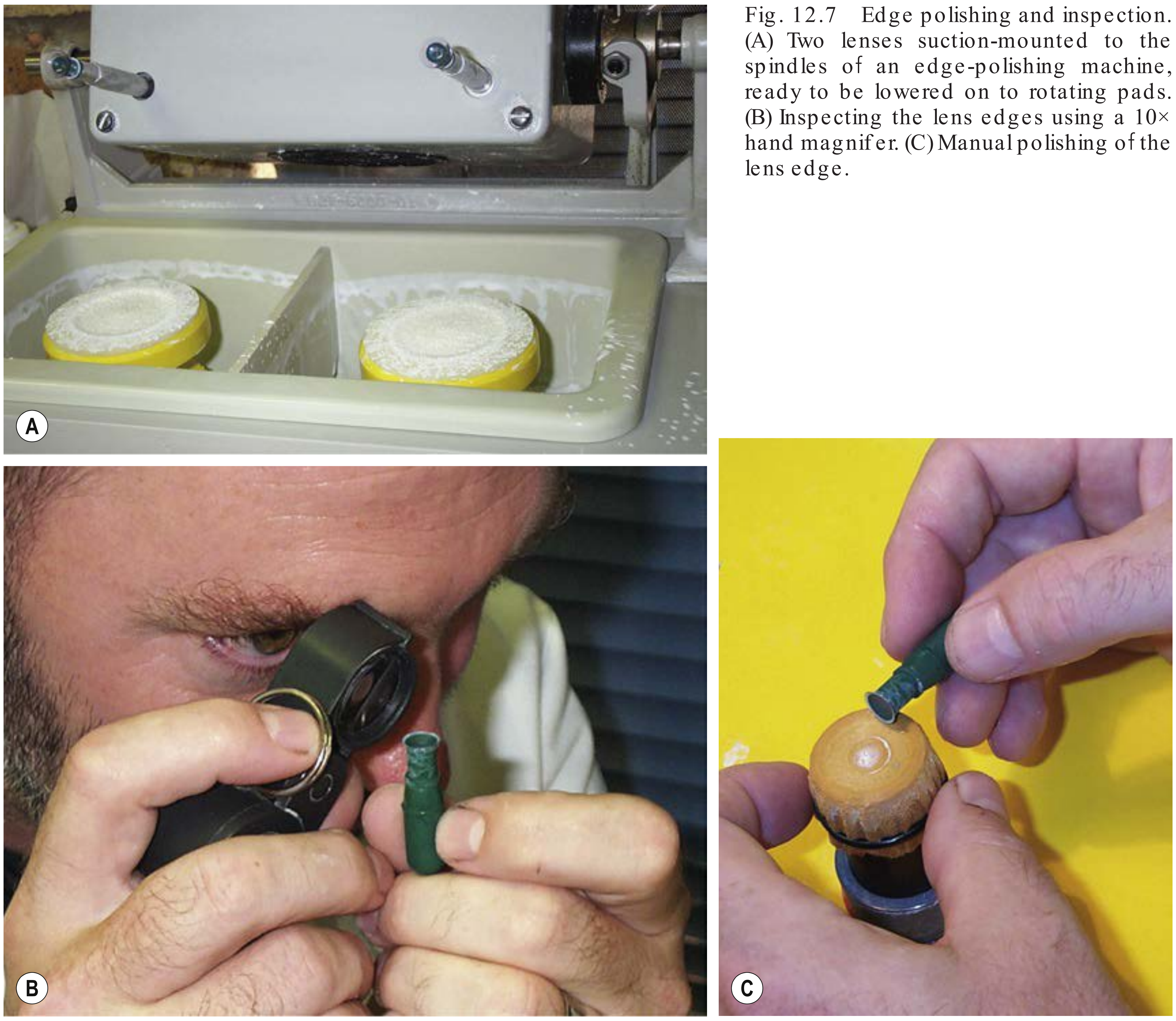

Fig. 12.7 Edge polishing and inspection. (A) Two lenses suction-mounted to the spindles of an edge-polishing machine, ready to be lowered on to rotating pads. (B) Inspecting the lens edges using a 10× hand magnifier. (C) Manual polishing of the lens edge.

An alternative direct-cutting technique involves the principle of pulsing either the diamond tool or the spindle containing the lens itself in an orthogonal axis to the lens surface that is to be cut. By adjusting the stroke length of the pulses in conjunction with the spindle revolution and feed rate, rotationally non-symmetrical shapes can be generated.

To generate a toric back surface using the technique of crimping, a spherical back curve is cut into the button in the usual way, except that a stepped rim is also engraved into the base of the blank. The curvature of this surface is the average of the required toric radii of the finished lens. The button is machined down to about 0.20 mm thick so that it can be flexed to the desired amount. The button is placed in a crimping tool with the concave surface facing upwards; this tool is a form of clamp that allows pressure to be incrementally applied to the rim of the button until it bends by a measured amount. The extent of bending is monitored optically using a conventional radiuscope.

The crimping assembly containing the flexed button is fixed to the spindle of a lathe and set spinning. A spherical surface is cut into the rotating flexed button. When the button is eventually released from the crimping tool, it reverts to its natural shape and the lathed surface assumes a toric form. The lens is blocked and a spherical curve can be generated on the front surface. Crimping is used again to generate a toric front surface if required. Orssengo et al. (1997c) have described how variations in crimping pressure and the preliminary radius of curvature of the back lens surface prior to crimping can influence the average back surface curvature and degree of toricity achieved.

ASPHERIC RIGID LENS MANUFACTURE

Aspheric surfaces can be generated for two main purposes:

1. To provide an enhanced lens fit, by more closely matching the aspheric surface of the cornea.
2. To provide a progressively changing power profile across the lens to correct longitudinal spherical aberration or presbyopia.

Modern lathing techniques enable these complex curves to be generated accurately and in a consistent manner.

REVERSE-GEOMETRY LENS MANUFACTURE

Reverse-geometry designs, in which the peripheral curves are steeper rather than flatter than the base curve, were not possible with older lathe technology. The ability to generate such profiles is required to produce lenses suitable for modern orthokeratology, where the flatter central curve is used to flatten the cornea, but the steeper periphery aids centration (see Chapter 32). It is now possible to generate steeper or flatter curves just in the periphery of the inferior quadrant to minimize or eliminate edge stand-off. Previously this might have been done manually, but the lenses were inherently almost impossible to reproduce.

Industry Regulation

In Europe, the control of contact lenses and contact lens care products is regulated by the European Medical Devices Directive. This directive sets out requirements to which each device must conform – there are thousands of medical devices covered by the directive – and the associated trade then devises appropriate management mechanisms to ensure the conformity of its products. Devices conforming to the directive should carry the European standard CE mark. Since June 1998, it has been illegal either to sell or buy a contact lens that does not have the CE mark affixed to it.

The CE marks are dispensed through what are called notified bodies. Companies wishing to affix the CE mark to their products must be registered as an approved manufacturer with a notified body, which will provide them with authority to use the mark. In order to get on the approved list of a notified body, manufacturers of contact lenses are generally required to have: (1) implemented a quality system, typically ISO 9002, and then (2) applied the medical device-specific CE requirements in the form of a further layer of bureaucratic controls set out in EN 46002. This procedure has become the de facto approach used by UK contact lens manufacturers who have obtained the CE mark for their products, and looks set to be the normal pathway for complying with the regulations. A principal activity of the notified bodies is to audit the device manufacturer to make sure that the procedures in use are such that devices made in the system comply with the directive.

An unfortunate outcome of working within a regulated industry is that new product development is a slower and more expensive process. Such regulations do not provide for the 'fast-track' approach of the 1980s, when new materials and designs moved rapidly from research and development to the clinic. Certainly, there has been a noticeable decline in the pattern of frequent releases of new highly permeable materials and innovative back surface designs into the marketplace since the new European regulatory framework came into being (Hough, 1997).

Conclusion

There is ever-increasing commercial pressure in the average optical practice to prescribe soft contact lenses, and a certain amount of peer pressure to do the same (Efron, 2010). Mass media consumer advertising by major soft lens manufacturers reinforces this trend by continuously highlighting the clear benefits of the comfort and convenience of disposable soft lenses. Modern contact lens lathes based on the latest developments in computer control systems and precision engineering have resulted in sophisticated designs that can address the most complex of ocular disorders.

The huge numbers of soft lenses produced to meet the requirements of disposable and frequent-replacement wearing modalities could easily give the impression that rigid lenses form a very minor part of contact lens practice; indeed, in the UK between 1996 and 2005, rigid lens new fits decreased from 22% to 4% (Morgan and Efron, 2006), and this low level of rigid lens prescribing has remained low, being 6% in 2015 (Morgan et al., 2016). However, even though rigid lens manufacture is labour intensive and expensive, the survival of this sector attests to the fact that there is an ongoing clinical requirement for rigid lenses. Other forces serving to preserve rigid lens sales include inertia in the prescribing habits of more traditional practitioners, demand from existing wearers who are satisfied with the product, trends towards frequent rigid lens replacement (see Chapter 20) and, perhaps most importantly, the willingness of some practitioners to embrace the challenges of specialty rigid lens fitting to achieve the best possible outcomes for their patients. Fortunately there appears to be a sufficient market for rigid lenses to enable the small, specialized manufacturers to survive.

ACKNOWLEDGEMENTS

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Access the complete references list online at http://www.expertconsult.com.

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13

Rigid Lens Optics

W NEIL CHARMAN

Introduction

Unlike soft lenses, which drape to fit the cornea so that on the eye the geometry of the back surface closely conforms to that of the anterior cornea, the back surface of a rigid lens maintains its shape. As a result, a tear lens of predictable form and power is generated between the contact lens and the cornea. The overall optical system producing the retinal image therefore effectively contains three elements: the rigid lens, the tear lens and the eye itself. We can imagine each of these elements as being separated from its neighbour by an infinitely thin film of air (Fig. 13.1A). This chapter is largely concerned with the role of the tear lens and the factors that influence its properties. Aberration will also be discussed. Questions of effectivity, spectacle magnification and related matters are addressed in Chapter 3.

Basic Tear Lens Properties

The power of the tear lens, sometimes called the liquid, fluid or lacrimal lens, depends on the relative geometry of the optic zone of the back surface of the rigid lens and the anterior surface of the cornea. Fig. 13.1B shows possible variations on the basic tear lens form. The tear lens may contribute negative, zero or positive power to the overall lens–eye system, depending on whether the fitting of the rigid lens is flat, in alignment or steep, respectively.

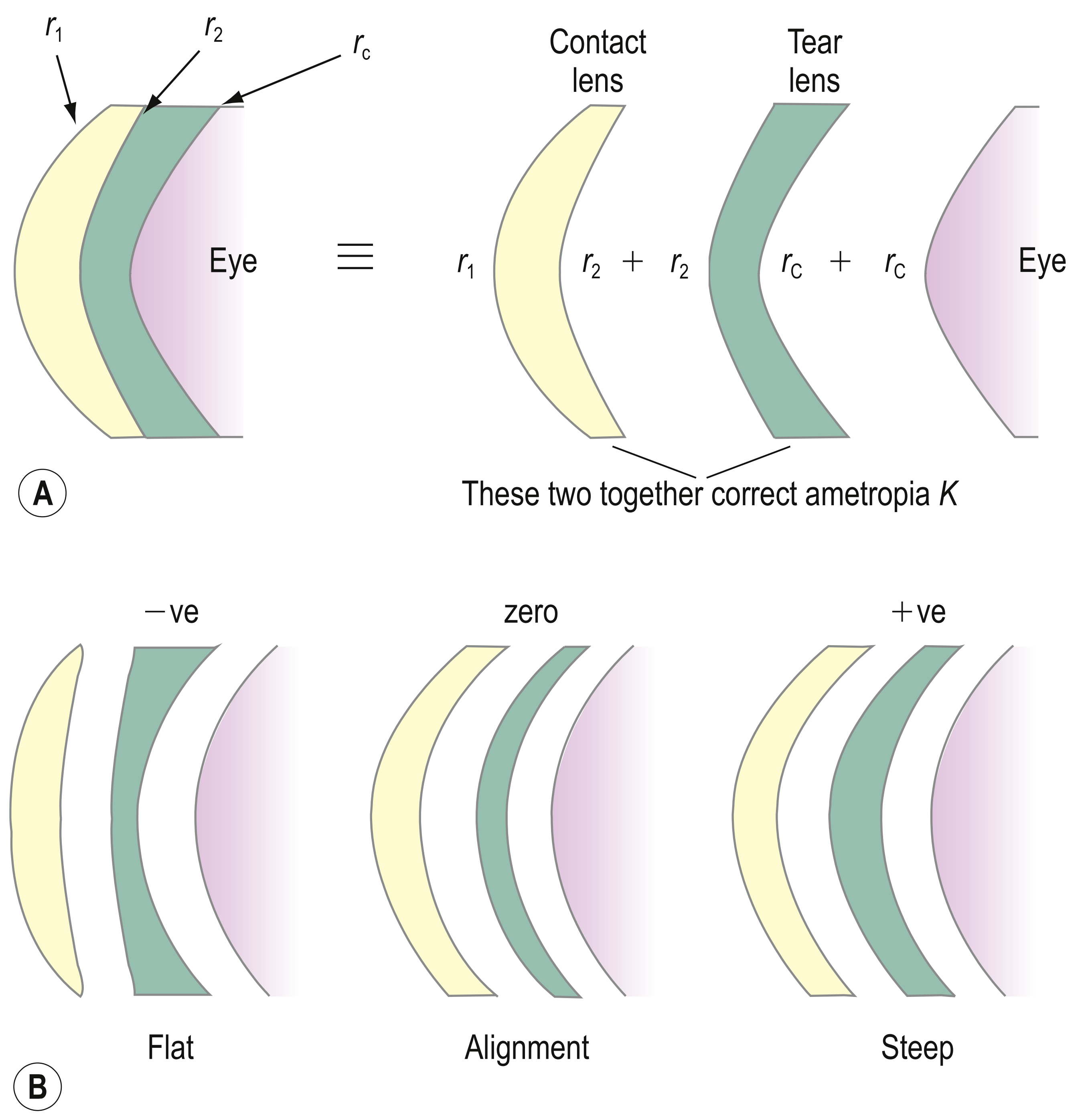

Fig. 13.1 (A) The basic tear lens concept. Although exaggerated for clarity, the air gaps between the contact and tear lenses and tear lens and cornea are effectively negligible. See text for definitions of r_1, r_2 and r_C. (B) Geometry of the tear lens as a function of fit.

From a clinical perspective it is important to determine the likely magnitude of the power of the tear lens and how it varies as the back optic zone radius (BOZR) of the lens is changed. If r_1 and r_2 are the front optic zone radius (FOZR) and BOZR of the rigid lens and r_C is the radius of the anterior cornea, then the front and back radii of the tear lens are r_2 and r_C, respectively. With corneal lenses it is reasonable to consider that the thickness of the tear lens can be neglected, so that its power, F_T, will therefore be:

$$F_T = (n_T - 1)(1/r_2 - 1/r_C) = (n_T - 1)(r_C - r_2)/r_2 r_C \quad \text{(Eq. 13.1)}$$

where n_T is the refractive index of the tears (1.336). Both r_2 and r_C will normally be about 8 mm. This gives, with adequate accuracy:

$$F_T = (1.336 - 1)(r_C - r_2)/(64 \times 10^{-6})$$

where the radii are in metres. Setting, as an example, $r_C - r_2 = 0.05$ mm, we find:

$$F_T \approx (0.336) \cdot (0.05 \times 10^{-3})/64 \times 10^{-6} \approx +0.25\text{D}$$

Thus, as an approximate rule of thumb, for a rigid lens the tear lens power increases by about +0.25 D for each 0.05 mm that the BOZR of the lens is steeper than the corneal radius. Correspondingly, on any cornea the back vertex power (BVP) of the rigid contact lens needs to be changed by −0.25 D for each 0.05 mm that the BOZR is made steeper, to compensate for the extra positive power of the liquid lens. If the lens BOZR is made flatter by 0.05 mm, the BVP needs to be changed by +0.25 D.

More exact calculation of F_T can, of course, be carried through using Eq. 13.1. The approximation is less acceptable for corneas that are much steeper or flatter than the normal value of about 7.8 mm. This can be seen if we note that, for small changes δr_2 in r_2, we can write for the change, δF_T, in tear lens power:

$$\delta F_T = (\delta F_T/\delta r_2)\,\delta r_2 = -[(n_T - 1)/r_2^2]\,\delta r_2$$

That is, for a given change in r_2, the change in tear lens power is actually inversely proportional to r_2^2.

The Tear Lens During Trial Lens Fit

Trial or diagnostic lenses are often used to find the BOZR that gives the required fit with a particular lens design – an over-refraction then being carried out to determine any additional power needed in combination with the trial lens used to give the patient clear vision. In this case the ordered lens power is simply the sum of the BVP of the trial lens and the overrefraction (assuming that the power of the latter is small enough for effectivity to be ignored; see Chapter 3). This is because the BOZR and corneal radii, r_2 and r_C, with the final lens will be exactly the same as with the trial lens, so that the tear lens has equal power in both cases (Fig. 13.2).

Required BVP when the Lens to Be Ordered has a Different BOZR from the Trial Lens Used

The situation may arise where a trial lens with a given BOZR is not available, in which case it may be necessary to order a lens with a BOZR that differs from that of the trial lens actually used. Since the BOZR, r_2, in the two cases differs, so also will the power of the tear lens, and this in turn will influence the required BVP of the ordered lens. This effect is best illustrated by an example (Fig. 13.3).

Suppose that the trial lens giving a fit that is closest to that desired has a BOZR of 8.10 mm and a BVP of −3.00 D. With this lens, an overrefraction of +1.00 D is found. Consideration of fluorescein patterns and the corneal radius, however, suggests that trial lens fit is too steep and that the ordered lens should have a BOZR (r_2) = 8.25 mm. Qualitatively, it can be seen from Fig. 13.3 that this flattens the front surface of the tear lens and hence tends to make its power less positive. To compensate for this, the final contact lens must have relatively more positive power. What is the required BVP for the ordered lens?

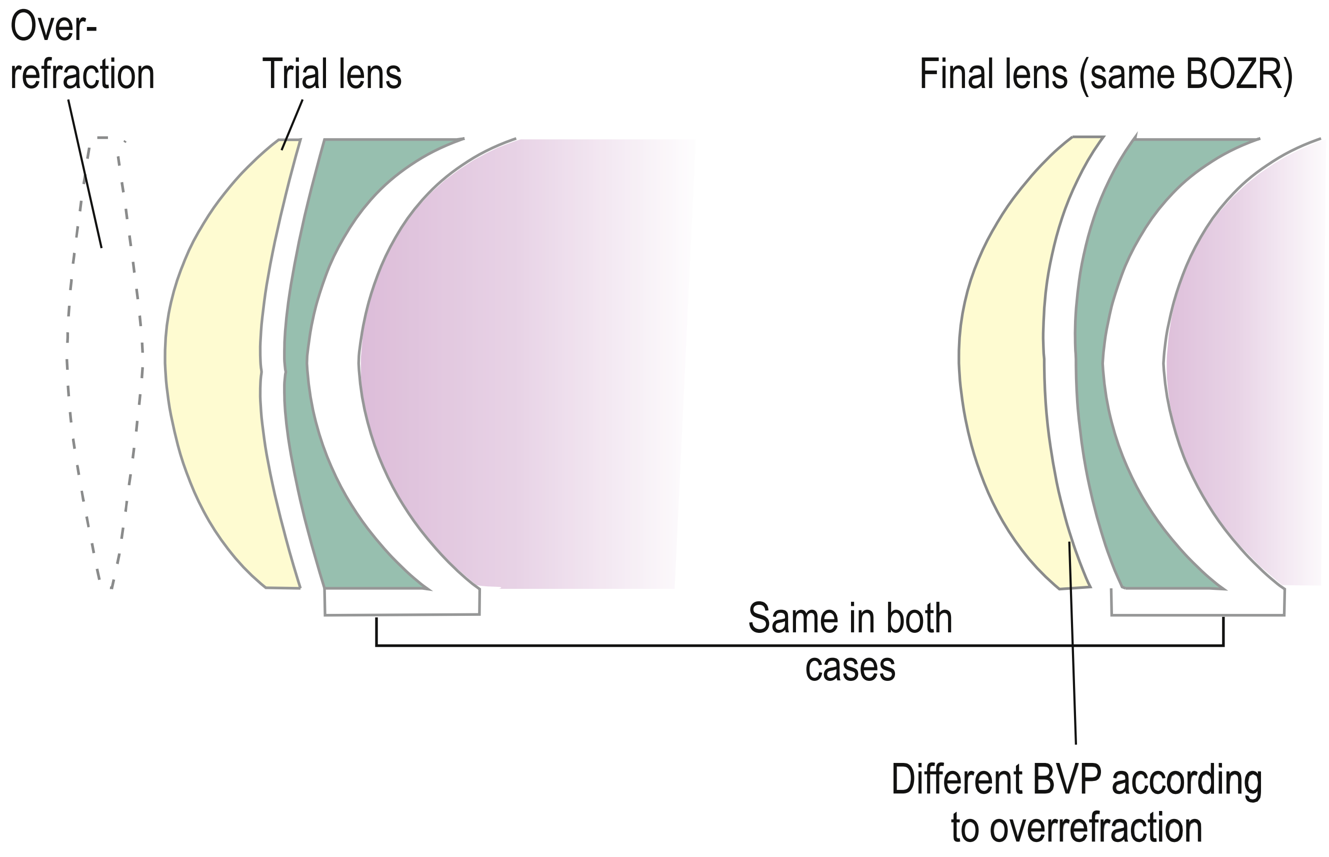

Fig. 13.2 Geometry of the rigid lens and the tear lens when a trial lens with the same back optic zone radius (BOZR) as the final lens is used. BVP = back vertex power.

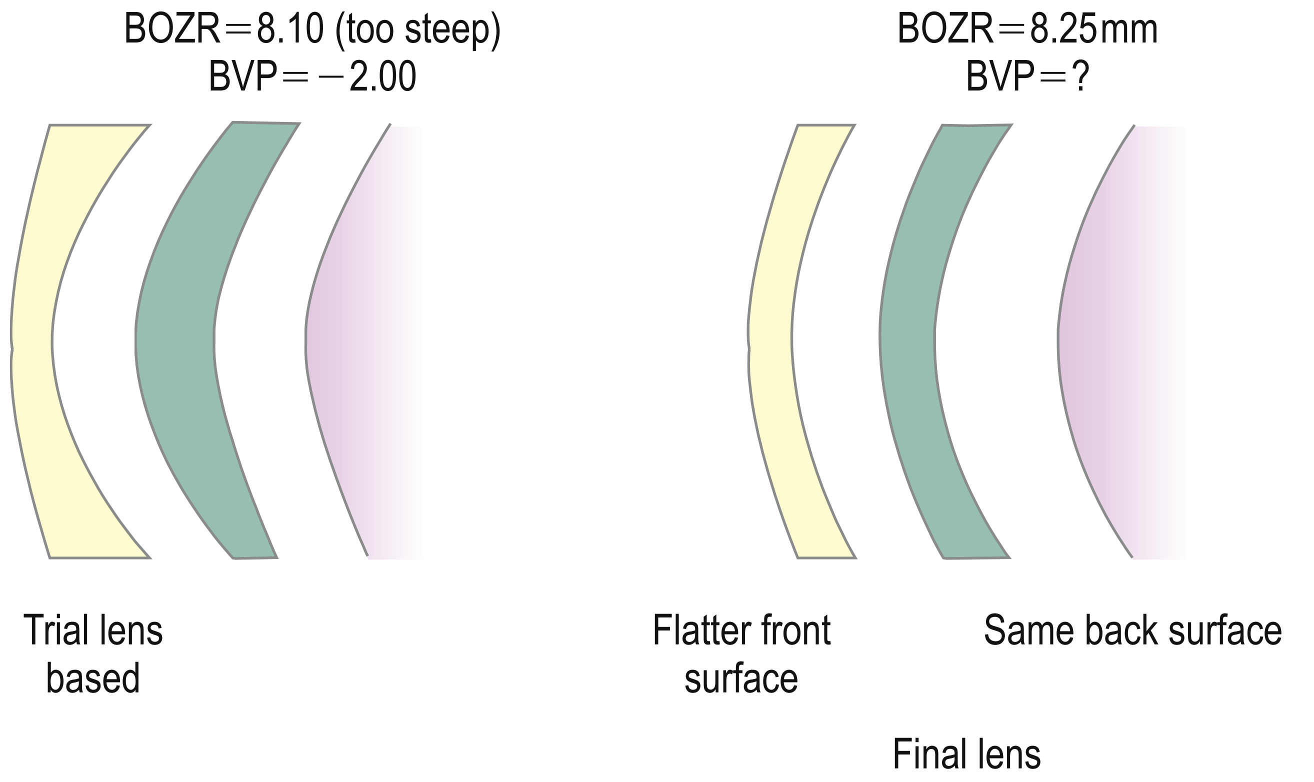

Fig. 13.3 Change in tear lens geometry and required back vertex power (BVP) when the back optic zone radius (BOZR) of the ordered lens differs from that of the trial lens.

Evidently, taking into account the BVPs of the trial lens and the overrefraction, the ideal BVP for a lens of the original 8.10 mm BOZR would be:

$$F'_V = -3.00 + 1.00 = -2.00\ \text{D}$$

Thus light would leave the back surface of the correcting lens of 8.10 mm BOZR with a vergence of −2.00 D. The power of the anterior surface of the original tear lens (in air) is:

$$(1.336 - 1)/(8.10 \times 10^{-3}) = +41.48\ \text{D}$$

Using the general vergence equation,

$$L' - L = F$$

where L and L′ are the object and image vergences, respectively and F is the surface power, we find that, after passing through the anterior surface of the tear lens, the vergence of the light would be:

$$-2.00 + 41.48 = +39.48\ \text{D}$$

If we assume that the tear lens has negligible thickness, this vergence incident upon the rear surface of the tear lens will correct the eye.

Now consider the ordered lens with a BOZR of 8.25 mm. Since the rear surface of the tear lens is unchanged, we again require that the vergence of the light leaving the anterior surface of the tear lens be +39.48 D. The power of the anterior surface of the new tear lens is:

$$(1.336 - 1)/(8.25 \times 10^{-3}) = +40.73\ \text{D}$$

Thus the vergence, L, incident upon the anterior surface of the tear lens must be:

$$L = L' - F = 39.48 - 40.73 = -1.25\ \text{D}$$

As this vergence is provided by the correcting lens, the required BVP for the ordered lens of BOZR 8.25 mm is −1.25 D (as compared with the value of −2.00 D for a lens of BOZR 8.10 mm). This agrees well with our earlier rule of thumb, which suggests that, as the BOZR is 0.15 mm (or 3 × 0.05 mm) flatter, the required BVP must be +0.75 D (or 3 × 0.25 D) more positive than its original value of −2.00 D – i.e. the required BVP is −1.25 D, as also found by the more exact approach.

Calculation of Required Surface Radii from a Trial Lens Fit

Assuming that the BOZR that gives the desired fit has been determined by the use of trial lenses, it is of interest to determine what value of FOZR, r_1, is needed to give the required BVP, given values for the centre thickness and refractive index for the lens. Again, it is helpful to give an illustrative example to demonstrate the thick lens calculation involved.

Let us suppose that it is found that a good fit is achieved with a trial lens of BVP −7.00 D and a BOZR of 8.00 mm. The overrefraction is −1.00 D at a vertex distance of 13 mm. The lens index is 1.49 and its centre thickness is to be 0.30 mm.

We are justified in ignoring tear lens effects as these are identical for the initial and final lens. As the overrefraction is small, effectivity can be ignored and the required BVP for our final lens is −8.00 D.

The power of the back surface of the final lens is:

$$F_2 = (1 - 1.49)/(8.00 \times 10^{-3}) = -61.25\ \text{D}$$

As we require the emergent vergence at the back surface to be:

$$F'_V = L_2' = -8.00 \text{ D}$$

the incident vergence at that surface, L_2, must be:

$$L_2 = L_2' - F_2 = -8.00 - (-61.25) = +53.25 \text{ D}$$

But $L_2 = 1.49/l_2$, so that the object distance, l_2, for the second surface is:

$$l_2 = 1.49/L_2 = 1.49/(+53.25)\text{m} = +27.98 \text{ mm}$$

Thus, for a centre thickness of 0.30 mm, the image distance for the first surface is:

$$l_1' = 27.98 + 0.30 = 28.28 \text{ mm}$$

and the corresponding image vergence is:

$$L_1' = 1.49/l_1' = 1.49/(28.28 \times 10^{-3}) = 52.69 \text{ D}$$

As, for a distant object, the incident vergence at the first surface is zero, the exiting vergence L_1' must correspond to the power of the surface, that is:

$$F_1 = (1.49 - 1)/r_1 = 52.69 \text{ D}$$

where r_1 is in metres. This gives $r_1 = 9.30$ mm. If a toric lens is required, the same process can be repeated in each principal meridian.

Neutralization of Corneal Astigmatism by a Rigid Lens of Spherical Power

We can see qualitatively that, in air, the astigmatism arising from a difference in the radii r_{C1} and r_{C2} in the two principal meridians of the anterior cornea is:

$$(n_C - 1)(1/r_{C1} - 1/r_{C2})$$

where n_C is the corneal index. If, however, the anterior cornea is in contact with the tears rather than air, this astigmatism is reduced to:

$$(n_C - n_T)(1/r_{C1} - 1/r_{C2})$$

Taking n_C as 1.376 and n_T as 1.336, we see that the astigmatism is likely to be reduced by a factor:

$$(n_C - n_T)/(n_C - 1) = 0.040/0.036 \approx 0.1\times$$

In fact the situation is slightly more complex than this because of the contribution of the rear surface of the cornea to the overall corneal astigmatism, but this does not alter the basic conclusion that corneal astigmatism can be almost completely neutralized by the use of a spherical rigid lens. An example will illustrate this (Fig. 13.4).

Suppose that the anterior surface of the cornea shows with-the-rule astigmatism, with:

$$r_{180} = 7.70 \text{ mm, giving power}$$

$$F_{180} = (1.376 - 1)/(7.70 \times 10^{-3}) = 48.83 \text{ D}$$

$$r_{90} = 6.93 \text{ mm, giving power}$$

$$F_{90} = (1.376 - 1)/(6.93 \times 10^{-3}) = 54.26 \text{ D}$$

Hence the astigmatism of the anterior surface of the cornea is:

$$F_{90} - F_{180} = 54.26 - 48.83 = 5.43 \text{ DC (with-the-rule)}$$

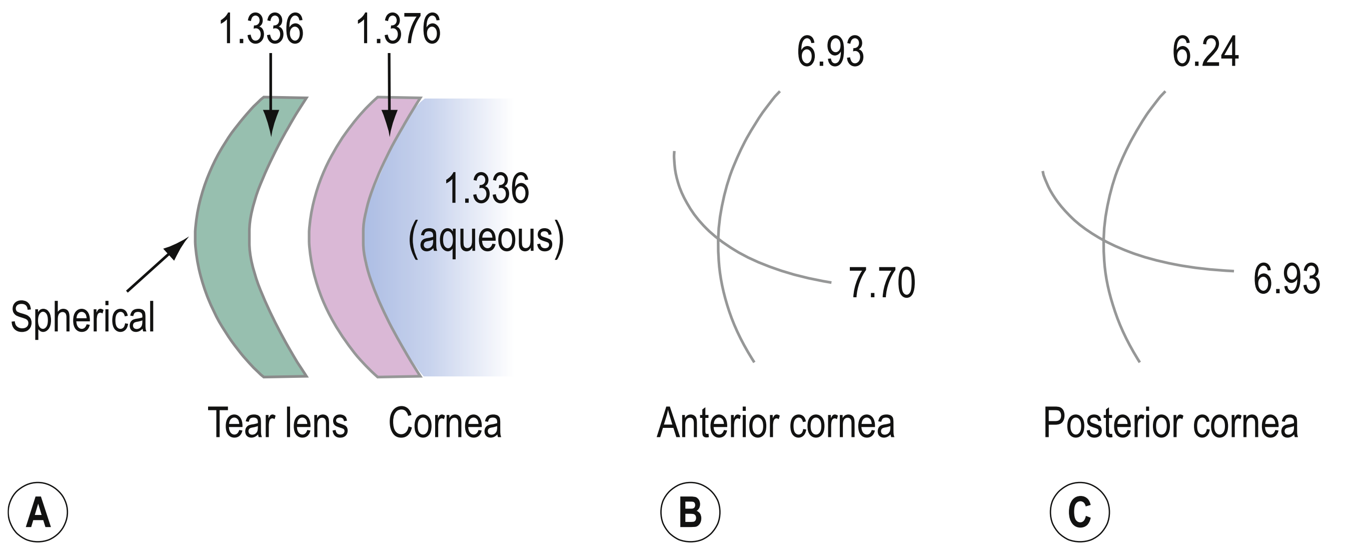

Fig. 13.4 Situation with a spherical contact lens on an astigmatic cornea. (A) Basic lens geometry; (B) anterior corneal and posterior tear lens radii (mm); (C) posterior corneal radii.

Now suppose that the posterior corneal radii are 10% smaller than the anterior radii (i.e. $r_{180} = 6.93$ mm, and $r_{90} = 6.24$ mm), and that the refractive index of the aqueous humour is 1.336. The posterior meridional powers will be:

$$F_{180} = (1.336 - 1.376)/(6.93 \times 10^{-3}) = -5.77 \text{ D}$$

$$F_{90} = (1.336 - 1.376)/(6.24 \times 10^{-3}) = -6.41 \text{D}$$

Thus the astigmatism of the posterior surface is:

$$F_{90} - F_{180} = -6.41 + 5.77 = -0.64 \text{ DC}$$

The total uncorrected corneal astigmatism is thus slightly lower than that due to the anterior surface alone, i.e.:

$$5.43 - 0.64 = 4.79 \text{ DC (with-the-rule)}$$

What is the effect of a spherical rigid contact lens? As the lens itself and the anterior surface of the tear lens can contribute only spherical power, they do not affect the astigmatism. The powers of the posterior surface of the tear lens are:

$$F_{180} = (1 - 1.336)/(7.70 \times 10^{-3}) = -43.64 \text{ D}$$

$$F_{90} = (1 - 1.336)/(6.93 \times 10^{-3}) = -48.48 \text{ D}$$

$$\text{i.e. } F_{90} - F_{180} = -4.84 \text{ DC}$$

When balanced against the astigmatism of the cornea, this leaves a mere $4.79 - 4.84 = -0.05$ DC of uncorrected astigmatism of corneal origin, so that the original corneal astigmatism has been almost completely neutralized. Note that this does not depend in any way upon the refractive index of the correcting lens. Any residual astigmatism due to the crystalline lens will, of course, remain uncorrected. Very occasionally a patient may be encountered who has a spherical refractive error but non-zero corneal astigmatism. This therefore implies that the residual (lenticular) astigmatism is of opposite sign to the corneal astigmatism and that correcting the corneal astigmatism with a spherical rigid lens will leave the residual astigmatism manifest. In such cases a spherical soft lens will result in better visual acuity, as the failure of the soft lens to correct the corneal astigmatism will allow the balance between the corneal and lenticular astigmatism to be maintained.

Although the above discussion has concerned regular astigmatism, it is obvious that irregular astigmatism and, indeed, general corneal irregularity will similarly be masked by a spherical lens and its accompanying tear lens (see below).

It is, however, important to note that, although nominally a spherical rigid lens will neutralize any value of corneal astigmatism, the fitting relationship is likely to be unsatisfactory for corneal astigmatism greater than about 2.00 DC. Thus for higher levels of astigmatism some form of toroidal correction is required (see Chapter 16).

Excellent expositions of further rigid and soft lens calculations of this type, together with many numerical examples, are given by Ford and Stone (1997) and Douthwaite (2005).

Aberrations of Rigid Contact Lenses

As in the case of soft lenses, the steep surface curvatures of rigid lenses mean that, if they remain well centred, their major aberration in relation to foveal imagery ought to be spherical aberration (Westheimer, 1961). Early calculations by Campbell (1981) emphasized that it was the aberration of the combined lens–eye system that was of importance, rather than that of the lens alone in air; it appeared that the dominant factor was the form of the front surface of the lens, although amounts of spherical aberration were likely to be low. Cox (1990) went on to demonstrate that levels of spherical aberration started to reduce visual performance significantly only for pupils larger than 6 mm and when rigid lens powers were more positive than −3.00 D. Hammer and Holden (1994) broadly agreed with these results and pointed out that, for conicoidally aspheric lens surfaces, on-eye aberration became more positive as the p-value of the front surface was increased and, to a lesser extent, more negative as the p-value of the back surface was increased.

Atchison (1995) made the important point that, although a well-centred aspheric contact lens might reduce the overall spherical aberration with respect to a lens with spherical surfaces, this advantage could break down if the lens decentred by more than about 1 mm, when substantial amounts of coma and defocus could be introduced, depending upon the exact lens parameters involved. Image quality with a spherical lens is generally more robust against decentration. This is illustrated in Fig. 13.5, which shows spot diagrams (i.e. retinal images of a point as calculated by ray optics) for the case of a +6.00 D lens and a 5 mm pupil. Various combinations of defocus and decentration are shown.

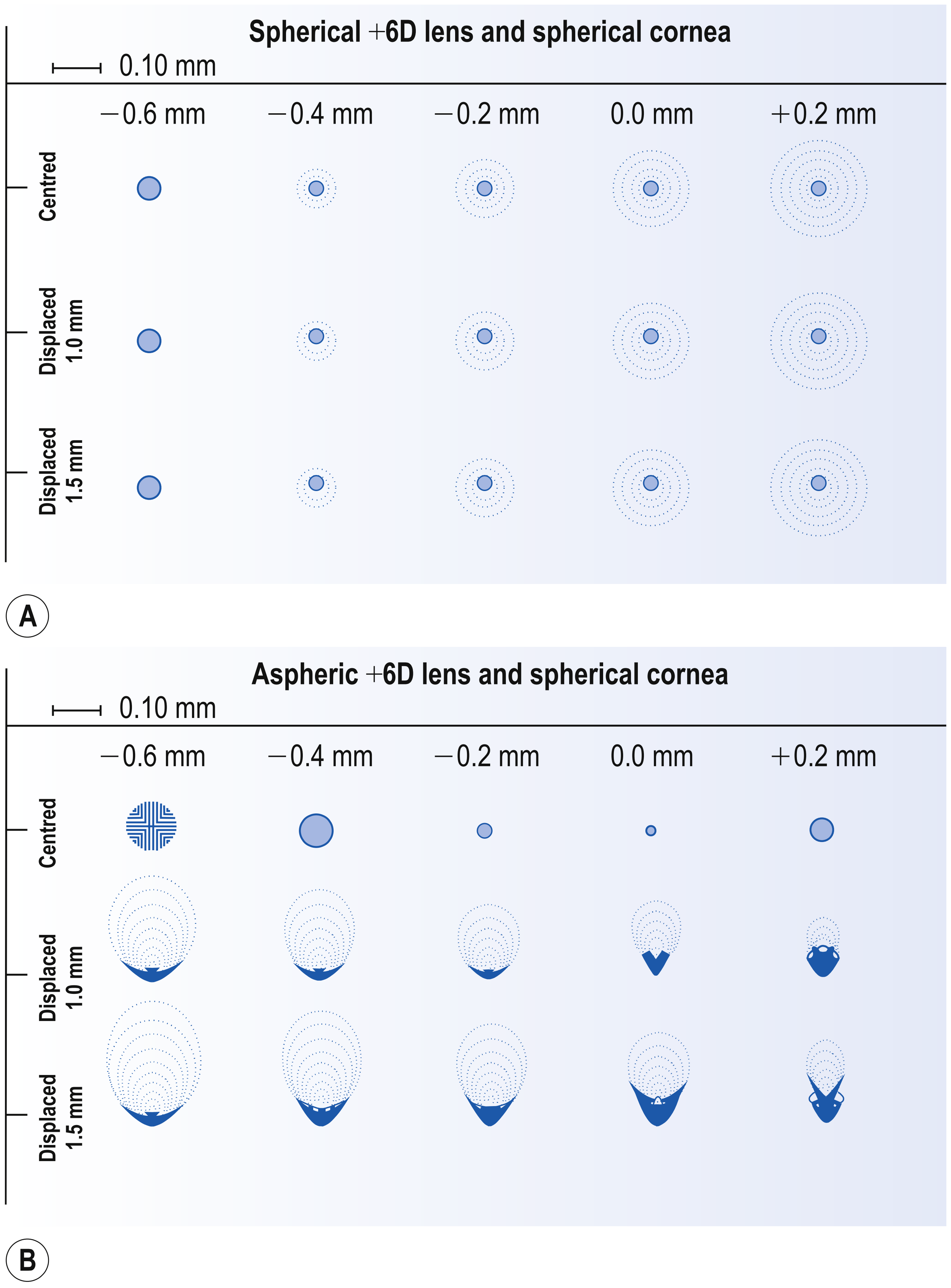

Fig. 13.5 Spot diagrams for a +6.00 D lens combined with a spherical cornea, as a function of defocus and decentration. Lens displacements are 0 mm (top row), 1.0 mm (middle row) and 1.5 mm (bottom row). Each row shows various planes of focus. The gaussian image plane is at 0.0 mm and negative values correspond to movement of the image plane towards the cornea. (A) Spherical contact lens. (B) Rigid contact lens with an aspheric front surface (p = +0.6): the chosen p-value nearly eliminates spherical aberration, giving minimal blur in the gaussian image plane (0.0 mm). (Adapted from Atchison, D. A. (1995) Aberrations associated with rigid contact lenses. J. Opt. Soc. Am. A, 12, 2267–2273.)

Relatively few earlier experimental studies explored the possible impact of the spherical aberration of rigid contact lenses on visual performance. Collins et al. (1992), however, found that when a group of 12 subjects was fitted with rigid lenses with front-surface asphericities corresponding to p = 1.0 (sphere), 0.74 and 0.49 (flattening ellipsoids), both high- and low-contrast photopic visual acuities were statistically identical with all lenses. In mesopic conditions, when pupils were larger, low-contrast visual acuity was significantly worse with the p = 0.49 lenses, but only by one line. Interestingly, when asked which lens they preferred, all except three subjects chose the lenses with a spherical (p = 1.0) front surface. Those who chose the lenses with p = 0.74 had demonstrably better visual performance with them than with the other lenses. Thus, although the effects of rigid lens spherical aberration on visual performance at photopic levels were generally small, there was some evidence that asphericities that optimized vision for the individual were appreciated by the wearer.

More recent work using wavefront aberrometry has clarified some aspects of the effects of rigid lenses on the combined lens–eye aberration in individual patients.

As discussed earlier, the effect of a spherical rigid lens and the associated tear lens is to neutralize almost all of the eye's original corneal astigmatism (i.e. the cornea's second-order astigmatic wavefront errors). The residual astigmatism associated with the crystalline lens remains uncorrected, however. In broad terms, it can be seen that similar compensation is likely to occur for the other higher-order aberrations associated with the asymmetries and irregularities of the cornea (Griffiths et al., 1998). The result is that, as far as the earlier parts of the contact lens–eye system are concerned, the original corneal aberrations become relatively unimportant and it is the aberrations associated with the anterior surface of the contact lens that dominate. However, the part of the original ocular wavefront aberration that was contributed by the crystalline lens will not be affected by the presence of the contact lens. Thus the overall wavefront aberration of the rigid contact lens–eye system will approximate to the sum of that due to the anterior surface of the contact lens and that due to the crystalline lens of the eye.

The impact of these rigid lens-induced changes will depend upon the balance between the contributions to the ocular wavefront aberration made by the cornea and the crystalline lens. How do these contributions compare? Intriguingly, recent studies confirm what had been suspected from earlier work (El Hage and Berny, 1973; Millodot and Sivak, 1979): in young adult eyes the aberrations of the cornea, particularly spherical aberration, tend to be of similar magnitude but opposite sign to those of the lens, so that the aberrations of the total eye are often smaller than those of its component parts (Artal et al., 2002; Kelly et al., 2004). However, the degree of balance between corneal and lenticular aberration varies between individuals and tends to deteriorate with age, largely as a result of increases in the wavefront errors of the crystalline lens. It appears likely that aberration-balancing occurs passively as a result of the basic optical design of the eye, rather than being an active process like emmetropization (Artal et al., 2006).

The key point is that elimination of corneal aberrations by a suitable design of contact lens does not necessarily reduce the wavefront aberration of the complete contact lens–eye system. Practical measurements of aberrations with eyes wearing rigid lens support this conclusion (Lu et al., 2003; Choi et al., 2007). Contact lenses may either reduce or increase the higher-order wavefront aberration compared with that of the original eye. Those subjects whose aberrations are dominated by high levels of corneal aberration are likely to have reduced aberrations with rigid lens wear, whereas those with low initial levels of both corneal and total aberrations may suffer from an increase in aberrations during lens wear. Rigid lens wear is, then, likely to be helpful in reducing the effect of higher-order aberrations in corneal conditions such as keratoconus (Griffiths et al., 1998; Dorronsorro et al., 2003; Choi et al., 2007; Jinabhai et al., 2012)

It is important to note that contact lens wear does not simply introduce changes in spherical aberration; it also affects coma and other asymmetric aberrations, presumably as a result of factors such as the lack of rotational symmetry in the cornea and decentration of the contact lens. What is not clear at the present time is the longer-term effect of rigid lens wear on lens–eye aberrations. Gross corneal warpage has long been recognized as a possible problem of rigid-lens wear (Efron, 2004) and it may be that some corneal change occurs in all eyes. Associated aberrational changes may be small, however, owing to the masking effect of the tear lens.

All recent authors (Hong et al., 2001; Dorronsorro et al., 2003; Lu et al., 2003; Choi et al., 2007) agree that aberrometry can provide a better understanding of the on-eye effects of rigid lenses on the vision of individual patients. Undoubtedly further studies will clarify the benefits of particular materials, lens designs and fitting philosophies in reducing aberration and increasing visual performance.

Other Rigid Lens Effects

Certain optical effects occur when rigid lenses move during wear, or are distorted over time, via interactions between the lids, the lens and the cornea. Disturbing optical effects can also result from reflections off the lens edge or optical zone junctions. These phenomena are considered here.

PRISMATIC EFFECTS DUE TO DECENTRED OR TILTED LENSES

Prismatic effects may arise as a result of the lens either decentring or tilting, the latter often being due to pressure from the upper lid. To a reasonable approximation, the corneal lens and the associated tear lens will both become decentred by the same amount with respect to the pupil centre, so that, applying the Prentice rule, $P = Fc$, where P dioptres is the prism power resulting from a decentration of c centimetres and F is the combined dioptric power of the contact lens and tear lens. If, for example, $F = \pm 10$ D and there is 1 mm of lens decentration, a 1 dioptre prism can be induced. This will be of little importance if similar effects occur in both eyes – that is, if the correcting powers are similar and fitting has ensured that similar amounts of movement occur in the two eyes. Fuller discussions of prismatic effects are found in Ford and Stone (1997) and Douthwaite (2005).

FLEXURE EFFECTS WITH RIGID CORNEAL LENSES

Although the basic assumption of this discussion has been that a spherically powered rigid lens remains so when placed on the eye, these lenses may flex on strongly toroidal corneas, particularly when the lenses are thin (Harris and Chu, 1972). This leads to a failure to correct the corneal astigmatism. Steps that may be taken to minimize flexure in such cases include fitting the BOZR as flat as possible and minimizing the back optic zone diameter. Flexure effects are difficult to predict and tend to vary as the lens moves on the eye; they are therefore best assessed empirically by direct objective and subjective determination of the effectiveness of the correction.

VISUALLY DISTURBING EFFECTS WITH RIGID LENSES

A number of disturbing visual effects may arise with some designs of rigid lens (Fig. 13.6). If the optic zone is small and the eye pupil is large, the outer zones of the pupil will be imperfectly corrected, leading to a 'halo' under dim lighting conditions. Similar effects may occur with smaller pupils if the lenses are badly decentred, so that the whole eye pupil no longer lies within the optic zone of the lens. In cases where the overall diameter of the lens is less than that of the cornea, discontinuities and flare light effects may arise in the peripheral field. Other

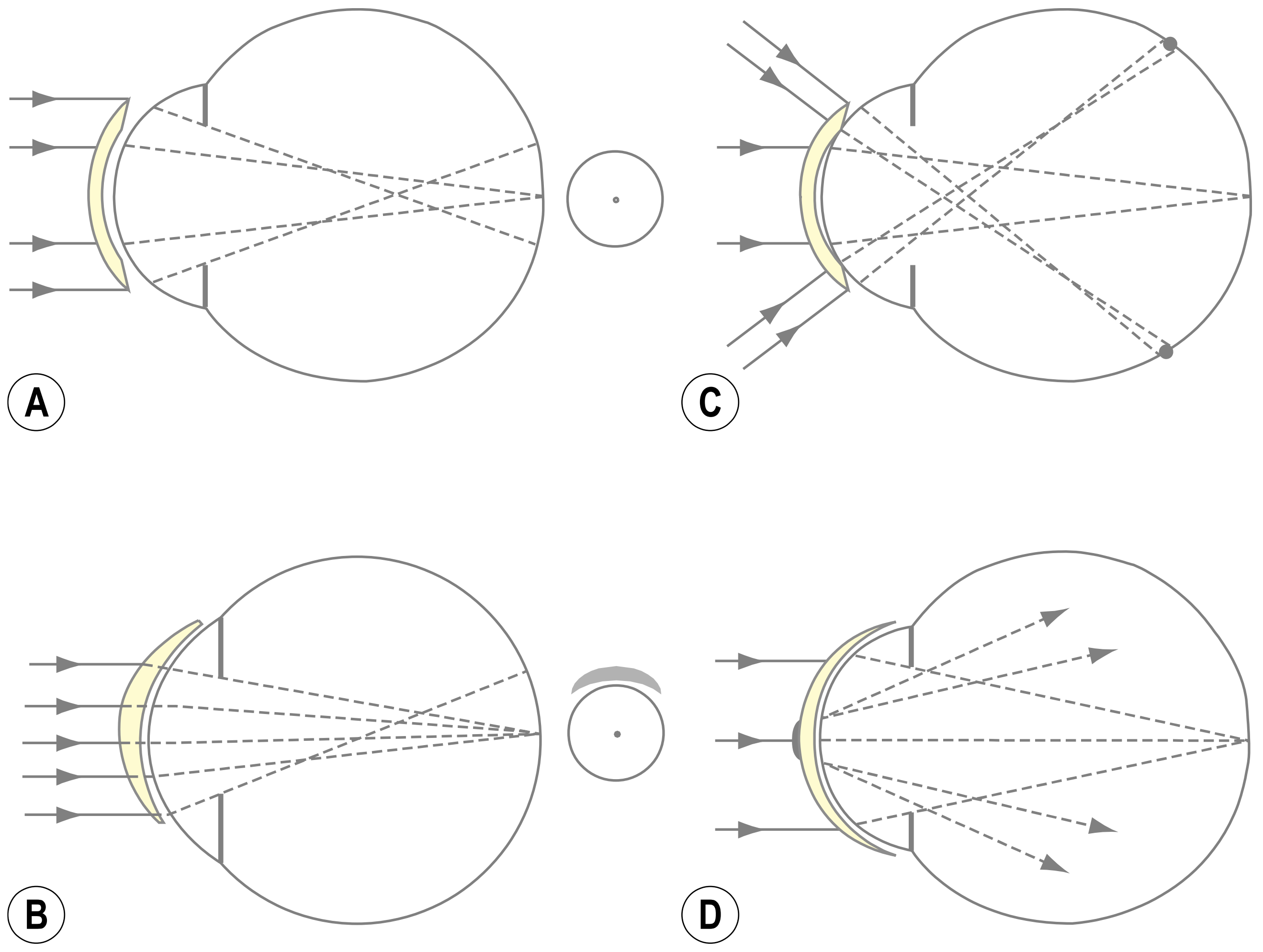

Fig. 13.6 Possible disturbing effects arising with rigid lenses. (A) 'Haloes' arising from the optic zone being smaller than the dilated pupil. (B) Asymmetric retinal point images due to a high-riding lens. (C) Disturbance of vision in the peripheral field due to scattering and refraction at the lens edge. (D) Scattering from lens deposits.

disturbing effects may result from lens deposits or, in the case of scleral lenses, from bubbles.

Conclusion

From the purely optical point of view, spherical-powered rigid lenses have the merit of correcting modest amounts of corneal astigmatism as well as any spherical refractive errors. As flexure effects are relatively slight, their performance is, perhaps, more predictable than their soft lens counterparts.

Access the complete references list online at http://www.expertconsult.com.

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14

Rigid Lens Measurement

KLAUS EHRMANN

Introduction

In contrast to soft lenses, rigid contact lenses are individually fitted and then lathe cut to meet particular optical, geometrical and material specifications (see Chapter 12). Although the manufacturing precision has improved significantly over the years, in particular with the introduction of computer numerical-controlled lathes, such improvements do not eliminate the need for careful lens inspection and measurements to ensure that only good quality lenses are fitted on the eye. This quality assurance rests predominantly with the lens laboratories, but contact lens practitioners should also be able to confirm basic lens parameters and detect faulty lenses.

The more experienced contact lens fitters occasionally modify rigid lenses to adjust the optical power, remove surface scratches or smoothen the edge profiles. Subsequent inspection is recommended to ensure that the modification was successful. The identification of unknown materials might be a further reason why practitioners and laboratories need to measure material related properties. Most aspects of contact lens quality are covered by ISO 18369 Parts 1–4 (International Organization for Standardization [ISO], 2006a, b, c, d) and laboratories are obliged to deliver only lenses that do not exceed allowable tolerances.

Based on shape, rigid contact lenses can be divided into scleral lenses (including corneo-scleral and miniscleral lenses) and corneal lenses. Optical features can include aberration control, astigmatic correction, or translating or simultaneous add powers for treating presbyopia. Orthokeratology lenses correct vision by reshaping the corneal surface. Each of these lenses has its own critical set of parameters and requires specific methods of inspection to ensure good vision and patient satisfaction.

The list of parameters that need to be checked on rigid lenses can be grouped into three main categories:

- Lens geometry:
  - Lens and optic zone diameters
  - Centre and edge thickness
  - Back and front surface radius of curvature
  - Edge profiles
- Optical properties:
  - Power and power profiles
  - Optical quality and surface defects
- Material properties:
  - Wettability
  - Friction
  - Oxygen permeability
  - Refractive index
  - Modulus
  - Luminance transmittance
  - Surface hardness.

Most rigid lens materials are relatively insensitive to ambient temperature and relative humidity, and can be measured under normal laboratory or practice environment conditions.

Lens Geometry

Despite being called ‘rigid’, finished rigid lenses can be very flexible and can deform permanently or temporarily when put under stress. It is therefore important to keep the lens free from external forces when measuring geometrical parameters (McMonnies, 1989). There have been reports to suggest that uptake of water or disinfection solution can also alter the shape of rigid lenses (Piccolo et al., 1990), but these effects appear to be minor and generally of no concern.

LENS AND OPTIC ZONE DIAMETERS

The V-gauge is a simple and easy-to-use method with adequate accuracy to measure the outside diameter of rigid lenses. A tapered channel is cut into a strip of plastic with diameter markings along the channel. Fig. 14.1 illustrates the use of such a device. The lens is placed in the wider opening on the right hand side and then gently notched towards the left until it touches the opposite side of the channel. The diameter value of the precalibrated scale is read from the position at which the lens touches the channel.

Projection systems such as calibrated loupes or slit lamps fitted with measuring graticules can also be used to measure lens diameters. They are reported to achieve a tolerance limit of 0.1 mm (Port, 1987) and have the advantage of being able to measure the diameter across several meridians, identifying possible lens warpage.

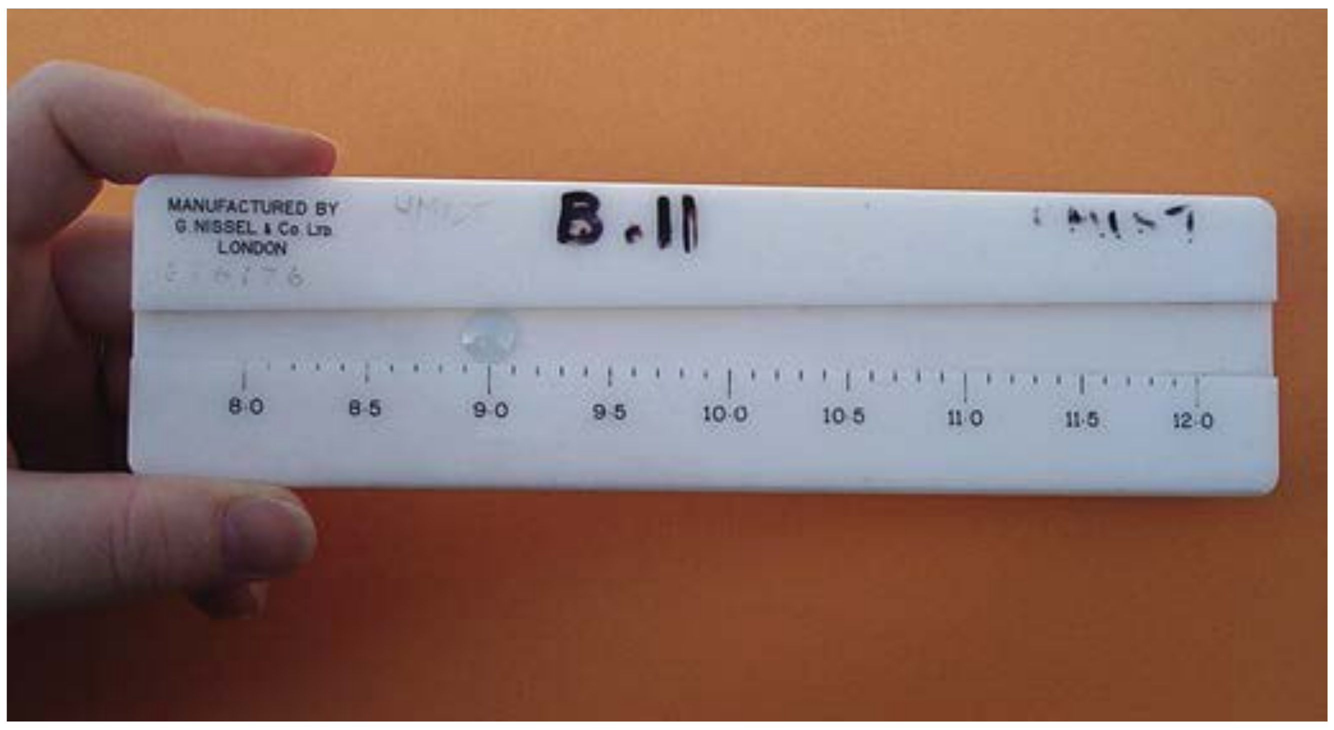


Fig. 14.1 Checking rigid lens overall diameter with a V-gauge. The lens is inserted into the wide opening of the V-shaped groove on the right, and allowed to slide down to the left until the gauge becomes too narrow for the lens to slide any further. The total diameter of the lens is read off the scale that runs along the lower border of the groove. In this case, the lens has a diameter of 9.0 mm.

With the correct illumination, distinct zones across the lens area can also be visualized and measured with projection systems. For more precise measurements, measuring microscopes or profile projectors can be used, providing a resolution of up to 1 µm.

CENTRE AND EDGE THICKNESS

The measurement of centre thickness provides key information on the rigidity of a lens and is also used to calculate oxygen transmissibility. Central, peripheral, and edge thickness can be measured using dial or digital gauges (Fig. 14.2). The gauges should have a readout resolution of 1 µm and a specified accuracy of ±3 µm. The anvil and the plunger need to be fitted with spherical ball tips with a radius between 1.2 and 5 mm. To minimize surface indentation and false thickness readings the measurement force should not exceed 1.4 N (ISO, 2006c). By moving the lens away from its central position, radial thickness readings can be obtained at selected peripheral and edge locations.

Optical and acoustic methods have also been used for measuring lens thickness on eye or on the bench. Ultrasound pachymeters are commonly used to measure axial length and corneal thickness. However, these instruments are limited in their resolution and acoustical properties of lens materials need to be known to correct the measured thicknesses. Optical methods face a similar constraints, but the conversion is made easier as the refractive index of lens materials is generally known. The two most commonly used optical methods are Scheimpflug photography and optical coherence tomography (OCT) imaging. For both methods, clinical instruments are commonly used for anterior segment imaging – for example, the Pentacam (Oculus, Germany) and the RTVue (Optovue, US), respectively. Either instrument can be employed to measure cross-sectional thickness profiles as well as complete thickness maps. The built-in analysis software converts the measured optical thickness into physical thickness using the corneal refractive index of 1.377. To obtain the actual thickness for a rigid lens, Eq. 14.1 is to be applied:

$$t_a = t_m \times \frac{1.377}{\mathrm{RI}_l} \tag{Eq. 14.1}$$

where t_a = actual thickness of rigid lens, t_m = measured thickness of rigid lens as displayed by instrument and RI_l = refractive index of rigid lens material.

By obtaining thickness profiles across several meridians, the amount of unwanted lens prism can be determined. Lens prism is a common deficiency with lathe-cut lenses. This defect is caused by a decentration of the front surface relative to the back surface due to inaccurate re-blocking of the button on the lathe.

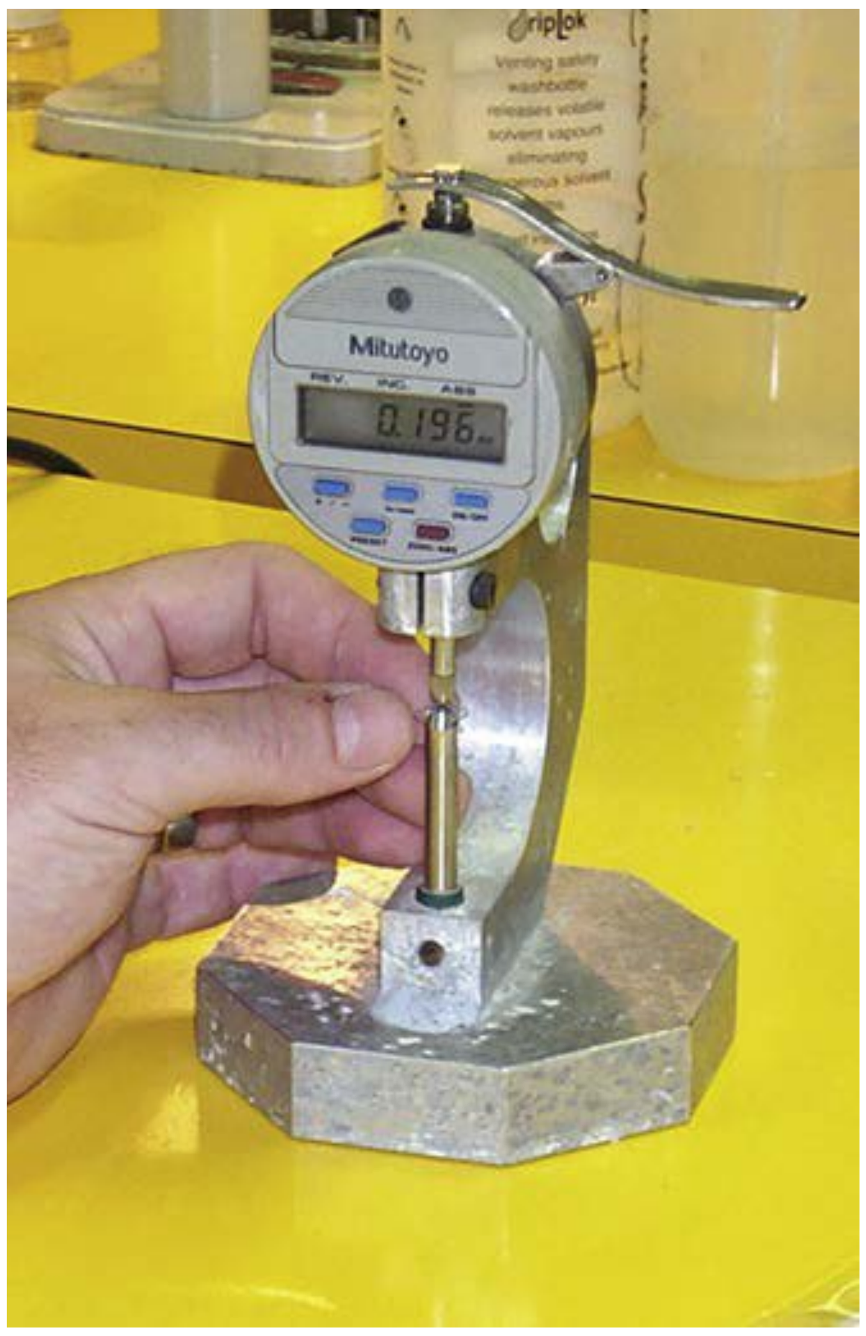


Fig. 14.2 Measuring rigid lens thickness using an electromechanical gauge.

BACK AND FRONT SURFACE RADIUS OF CURVATURE

The standard instrument with which to measure the radius of concave or convex surfaces on rigid lenses is the radiuscope. The operating principle of the radiuscope is explained in Fig. 14.3. Rays from the illuminated target are projected onto the surface via a beam splitter. At the in-focus position A, the reflected target is seen through the eyepiece as a clear, sharp image. In position B, the rays are reflected perpendicularly to the lens surface and also generate a sharp image. The relative distance between A and B corresponds to the radius of curvature. This operating principle applies to convex as well as concave surfaces.

The steep and flat radii of toric surfaces can also be measured by orienting the respective meridians with the vertical and horizontal line of the target and bringing each one in focus alternately. As many surfaces are now manufactured as aspheric ellipsoids or paraboloids, the target images in position B won't be in sharp focus and only an average radius can be determined. Should more detailed surface information be

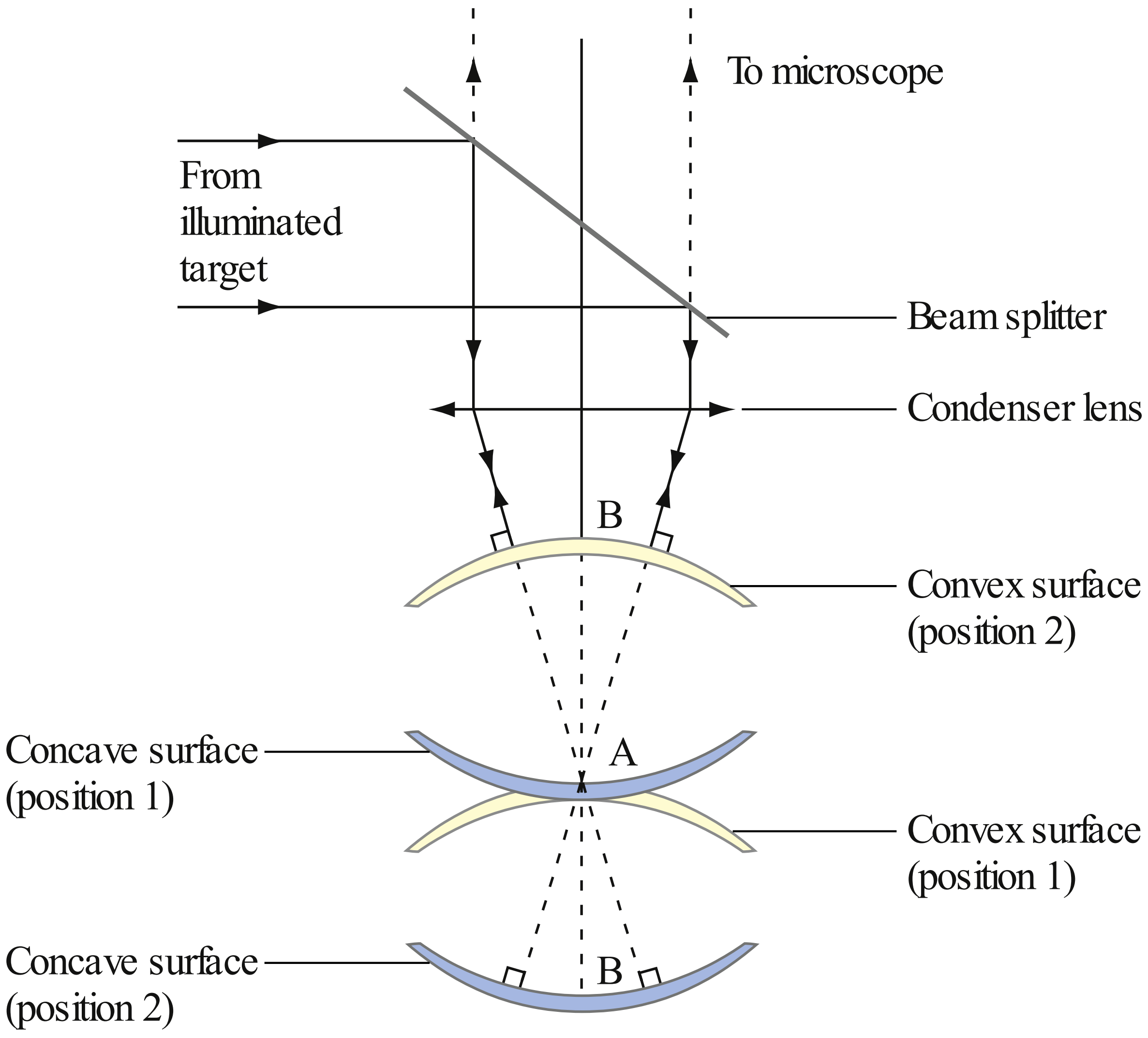

To microscope
From illuminated target
Beam splitter
Condenser lens
B
Convex surface (position 2)
Concave surface (position 1)
A
Convex surface (position 1)
Concave surface (position 2)
B

Fig. 14.3 Operating principle of the radiuscope for measuring convex or concave curvatures.

required, radii analysers such as the Brass 2000 (Rotlex, Israel) that utilize Moiré deflectometry can generate topographic maps and extract surface profiles with fitted mathematical functions. This methodology is particularly useful for manufacturers of orthokeratology lenses. The precise cutting of the complex back surface profile is critical to achieve the targeted corneal reshaping.

The keratometer is a clinical instrument that can also be used to measure front and back radii of rigid lenses. To minimize interfering reflections it is best to use a folding mirror and place the rigid lens horizontally, with a drop of water on the surface facing downwards (Fig. 14.4). Keratometers measure the curvature at only two defined points, usually about 3 mm apart. Any asphericity cannot be captured, but toric surfaces can be measured by rotating either the instrument or the lens to determine the steep and flat meridians. Kumbar et al. (2012) showed that keratometer measurements agree well with results obtained by a radiuscope, with the mean difference being less than 0.03 mm.

Corneal topographers like the Humphrey Atlas (Carl Zeiss Meditec, Germany) have successfully been used to measure the curvatures of rigid lenses, including aspheric and toric surfaces (Elder and Benjamin, 2009). Elder and Benjamin found that this instrument measures within the base curve tolerance of 0.05 mm. However, not all topographer instruments are suitable to measure concave surfaces. When an appropriate instrument is lacking, an impression can be taken from the back surface and then measured as a convex surface.

Complete cross-sectional surface profiles can also be obtained by Scheimpflug and OCT based imaging instruments (see Thickness section above). Some instruments have built-in curve fitting algorithms or provide data export options for external analysis. The sharpness of junctions between different zones on the lens can also be determined using the appropriate analysis tools. To avoid optical distortions, the surface to be measured should face the instrument.

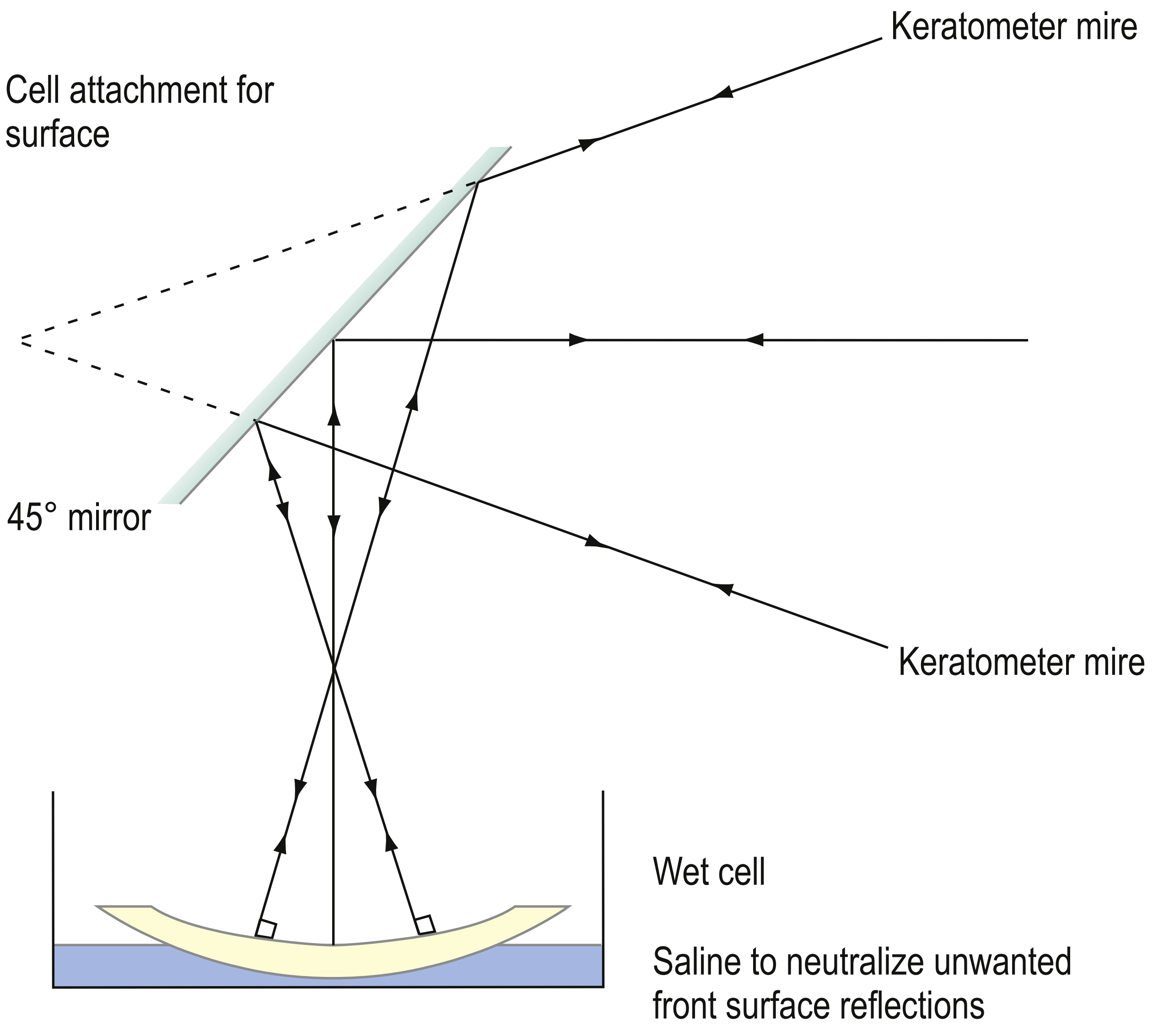

Keratometer mire
Cell attachment for surface
45° mirror
Keratometer mire
Wet cell
Saline to neutralize unwanted front surface reflections

Fig. 14.4 Use of the keratometer for measuring the concave (back) surface of a rigid lens.

EDGE PROFILES

The edge shape can be of critical importance for rigid lenses with respect to on-eye comfort (La Hood, 1988). The relative position of the apex, the sharpness of the anterior and posterior edge radii and edge thickness are features that can be inspected by practitioners using readily available equipment. Henry and Barr (1990) used a simple projection magnifier with graticule to check the edge profile. To better visualize the posterior edge shape, a slit lamp can be used to illuminate and observe a narrow section of the entire edge profile. A lens-holding device as used by Caroline et al. (1991) assists with the rotation of the lens to observe profiles around the circumference of the lens (Fig. 14.5). This ability to rotate the lens is a critical aspect, as most lenses are made with some degree of unwanted prism, which has a major impact on edge thickness and edge shape. Full inspection is also required to detect any chipping and dents or other localized defects.

La Hood (1988) also recognized the importance of checking edge shape at different meridians when she developed a moulding technique to obtain impressions of edge profiles. The entire edge of the rigid lens was pressed into a blob of quick-setting dental mould material. After setting, the lens was popped out and the mould sliced in four quadrants with two razor blades pressed against each other. The slices obtained could be viewed under a microscope and images taken for further analysis and documentation. La Hood (1988) classified edges as sharp, blunt, round or square.

For full edge shape quantification, Ehrmann et al. (1998) developed an optical profiler that measures complete cross-sectional lens profiles along several meridians, including high-resolution edge profiles. The self-guided optical sensor moves along the lens profile, recording data points with micron precision. Mathematical algorithms are then used to analyse the profiles and extract numerical parameters for quality assessment and classification.

By measuring edge profile and back surface with this instrument, the axial and radial edge lift can also be obtained from the collected data sets. As shown in Fig. 14.6, edge lift is the distance between the extended back optic zone radius and the apex of the edge, in either radial or axial direction, and can be calculated using measured parameters of lens diameter, back sag and back optic radius:

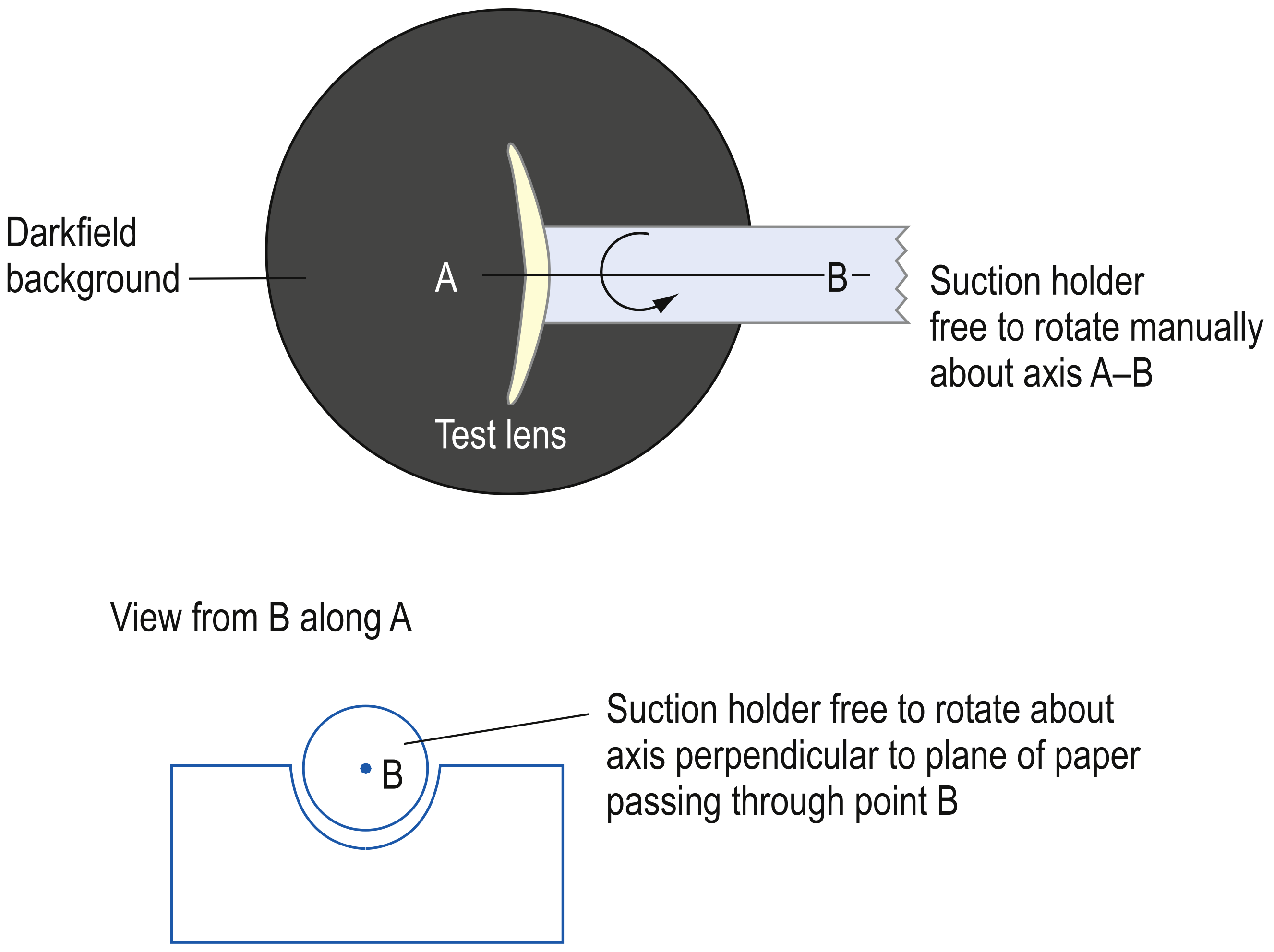
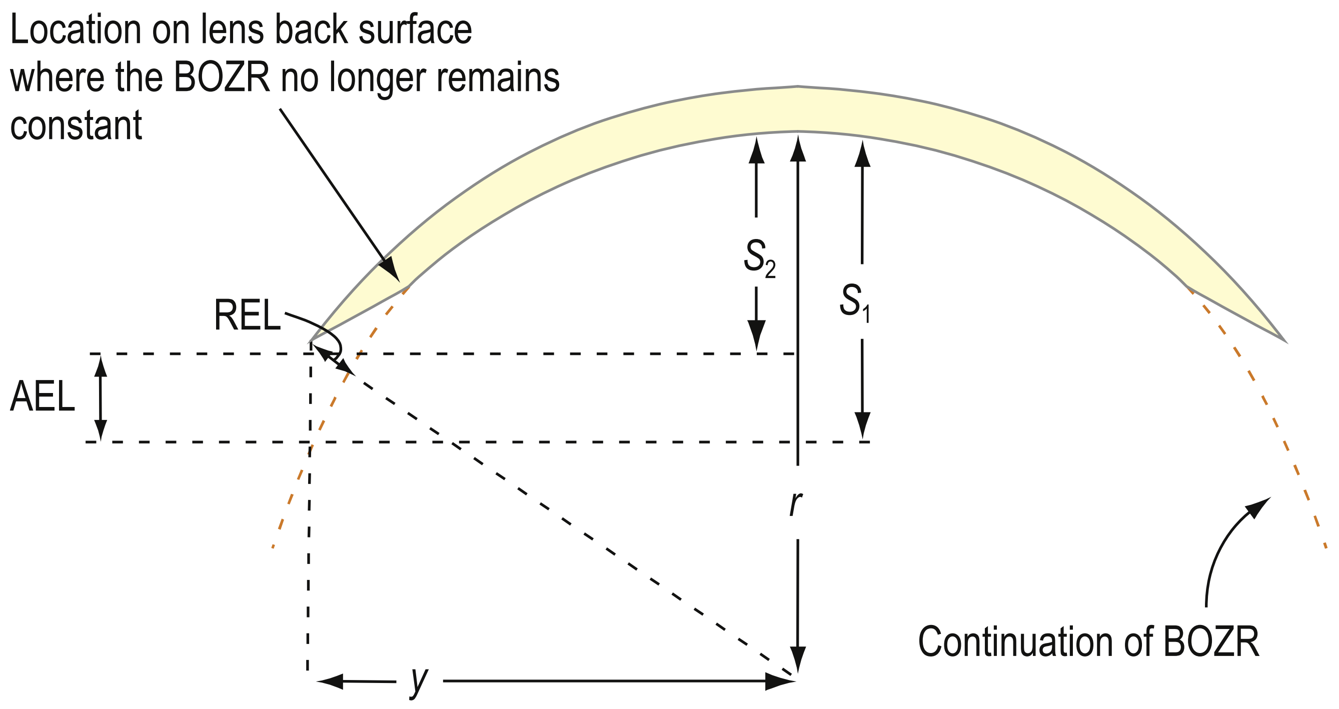

Darkfield background
A
B
Suction holder free to rotate manually about axis A–B
Test lens
View from B along A
B
Suction holder free to rotate about axis perpendicular to plane of paper passing through point B

Fig. 14.5 Lens edge-viewing device.


Location on lens back surface
where the BOZR no longer remains
constant
REL
AEL
S_2
S_1
r
y
Continuation of BOZR

(y=half overall diameter of lens)

Fig. 14.6 The form of the edge of a rigid lens can be defined in terms of either axial edge lift (AEL) or radial edge lift (REL). This nomenclature applies to all lens powers and designs. BOZR= back optic zone radius.

$$\mathrm{REL} = \sqrt{[(r - s_2) + y^2]} - r \qquad \text{Eq. 14.2}$$

$$\mathrm{AEL} = s_1 - s_2 \qquad \text{Eq. 14.3}$$

where:

$$s_1 = r - \sqrt{r^2 - y^2}$$

For lenses with an aspheric back optic surfaces, r needs to be replaced with the average back optic zone radius to obtain a meaningful edge lift value. For certain lens fitting philosophies, such as the lid attachment method (Korb and Korb, 1970), edge lift is a critical parameter and needs to be determined to troubleshoot poorly fitting lenses.

Optical Properties

In clinical practice, the optical performance of a rigid lens can be assessed in vivo, either subjectively by means of overrefraction or objectively with the use of autorefractors or double-pass wavefront analysis. This in vivo testing has the advantage of taking into account patient-specific factors such as lens centration and tear lens effects, making it a good measure for visual satisfaction. However, to track manufacturing quality and to troubleshoot poor visual performance, objective methods are required to quantify the optical parameters.

POWER AND POWER PROFILES

The standard focimeter is a suitable tool with which to measure the sphere and cylinder power of rigid lenses (Fig. 14.7). As described in ISO 18369-3 (ISO, 2006c), a 4.5 mm aperture stop should be used to minimize errors due to the highly curved back surface of rigid lenses. In particular, in order to obtain the correct back vertex power for high-powered lenses, correction factors might be required if the back surface curvature differs significantly from a standard 8.00 mm radius. The cylinder power and axis can also be determined by measuring the steep and the flat meridian power, either turning the lens or the mire with reference to the lens marking. The amount of optical prism can also be estimated using the focimeter. The instrument should be calibrated using a series of certified calibration lenses with 8.00 mm base curve.

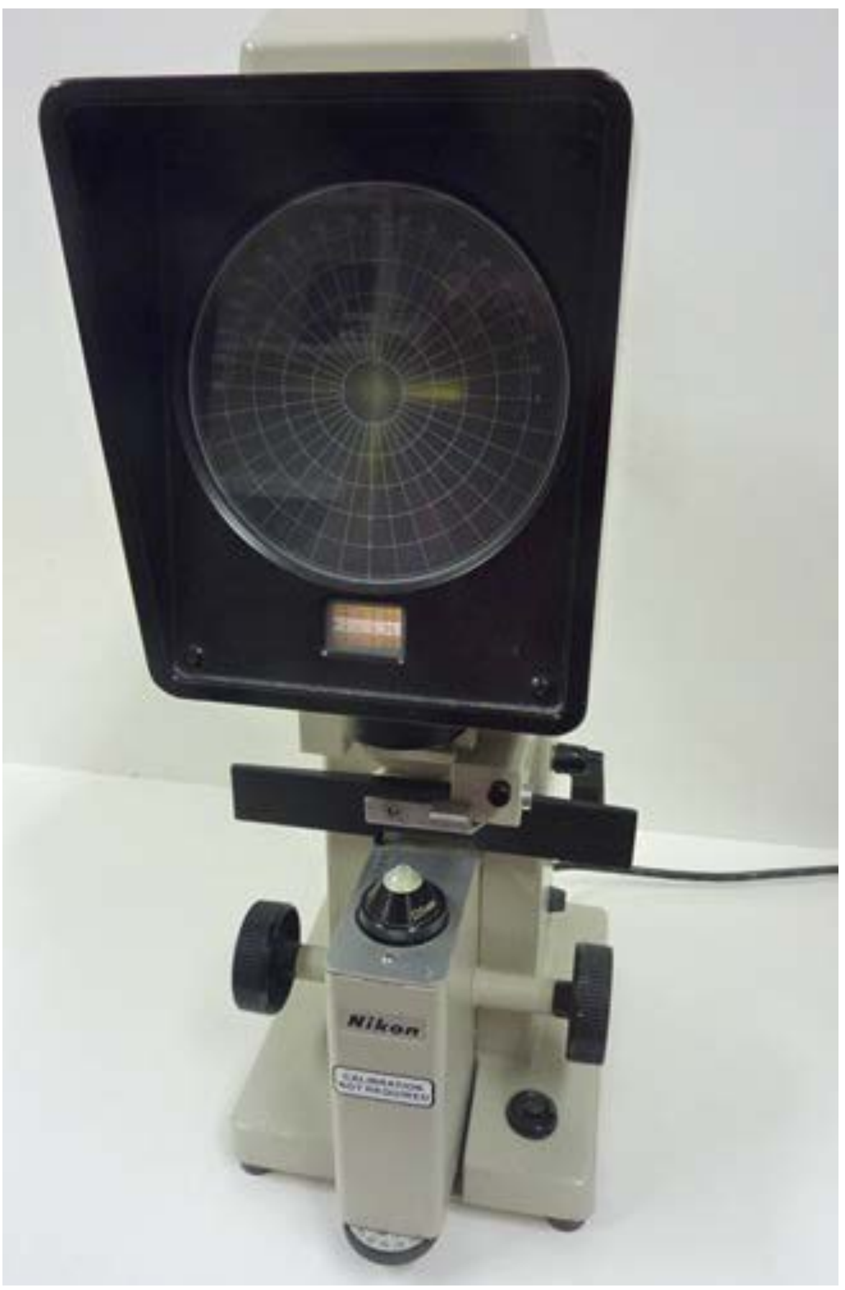


Fig. 14.7 Manual focimeter with contact lens support. (Courtesy of Nikon.)

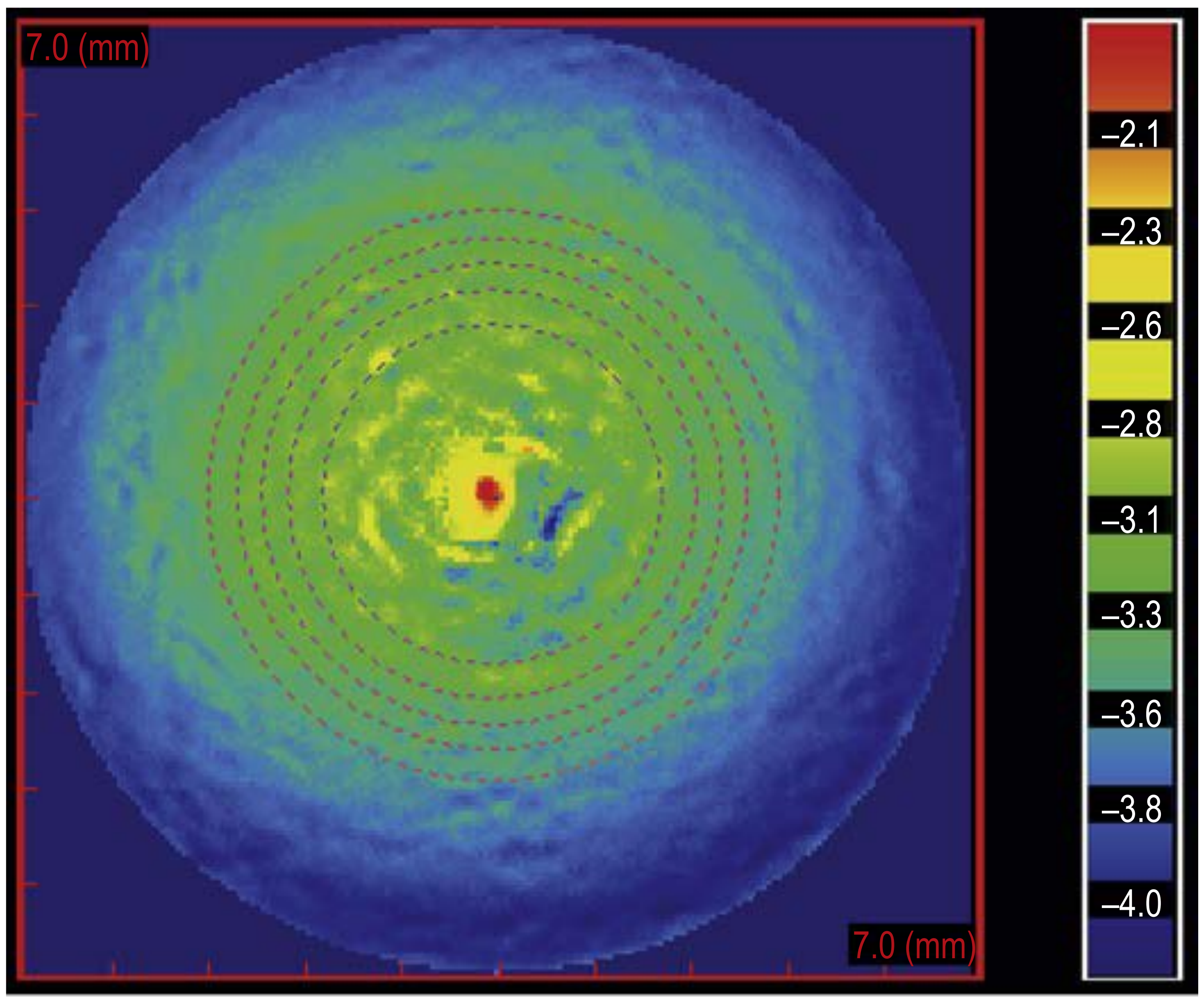


Fig. 14.8 Colour-coded power map obtained with Nimo TR1504 (colour scale is in D).

The quality of the projected target image provides some indication on the optical design of the lens or its surface quality. In particular, simultaneous multifocal lenses will generate a target image that cannot be brought into sharp focus. To measure these lens types accurately, or even translating bifocal lenses, wavefront-sensing instruments are required. The three common methods implemented in commercial lens mapping instruments are Hartmann–Shack (SHSOphthalmic, Optocraft), Moiré deflectometry (Contest Plus II, Rotlex) and phase-shifting Schlieren (Nimo TR1504, Lambda-X). All of these instruments map the refractive power of the entire optical zone, from which numerical parameters such as lower-and higher-order aberrations (Zernike coefficients), power profiles and optical defects can be extracted (Fig. 14.8). Depending on the selected method employed to convert the measured power into back vertex power, additional measured or assumed lens parameters of centre thickness, base curve radius, sag or refractive index might have to be provided.

OPTICAL QUALITY AND SURFACE DEFECTS

The power-mapping instruments listed above also calculate a relative optical quality number based on the optical irregularities within the optic zone. However, this optical quality number is based on standard single-vision designs. More complex toric, multifocal or orthokeratology lenses should be inspected manually by examining the colour-coded power maps or averaged power profiles to detect optical distortions. Optical distortions can be caused by uneven surfaces or local changes in refractive index due to overpolishing (Walker, 1989; Ho and Ehrmann, 2000). Finer surface defects such as lathe marks or scratches can best be visualized under the dark-field microscope. Tranoudis and Efron (1996) used the Optimec Contact Lens Analyser (Optimec, UK) to capture images of scratched surfaces and then quantified the scratching using image analysis software. Instruments based on the knife-edge principle (Ho and Ehrmann, 2000) visualize both power and surface defects although they cannot distinguish whether the defect is on the front or back surface. None of these instruments, dedicated for examining either soft or rigid contact lenses, is yet commercially available.

Material Properties

The measurement of material properties is generally outside the realm of practitioners. Material manufacturers publish all the relevant information and there is little scope for these parameters to change from their nominal values. With the exception of wettability, friction and modulus, ISO 18369 Parts 2, 3 and 4 prescribe the measurement methods and tolerances for material properties. Because of the specialized nature of these measurements, laboratories often develop their own instrumentation in compliance with the ISO recommendations.

WETTABILITY

Good surface wettability is required to maintain a stable pre-lens tear film and with it, good vision and ocular health. In vivo observations using a slit lamp or tearscope (Keeler, USA) are the clinically most relevant assessments (Guillon, 1998), although they lack the quantification of the material property itself. Measuring the contact angle of a sessile drop as described by Bush et al. (1988) is the most common in vitro method to establish wettability, not only of contact lens materials. Whereas Bush used a laser beam as optical pointer to read the contact angle, commercial instruments such as the Theta Optical Tensiometer (Biolin Scientific, USA) capture a magnified image of bubble and lens surface and automated image analysis determines the contact angle. These instruments also have the advantage of precise control over the size of the water or saline drop, which can affect the measured contact angle. Further refinements include the measurement of the receding or advancing angles.

Shirafkan et al. (1995) took a different approach by measuring the adherent mass of the drop of liquid on the front surface of a rigid lens after immersing and removing the surface from the liquid. They found that there are significant differences not only between materials, but also within the same material depending on its conditioning, whether stored dry in air, or soaked in water. Maldonado-Codina and Efron (2006) expanded on this method by measuring the adherence force of the meniscus as well as the maximum length the meniscus could be stretched before breaking. Although they tested only hydrogel lenses, the same method can be applied to rigid materials.

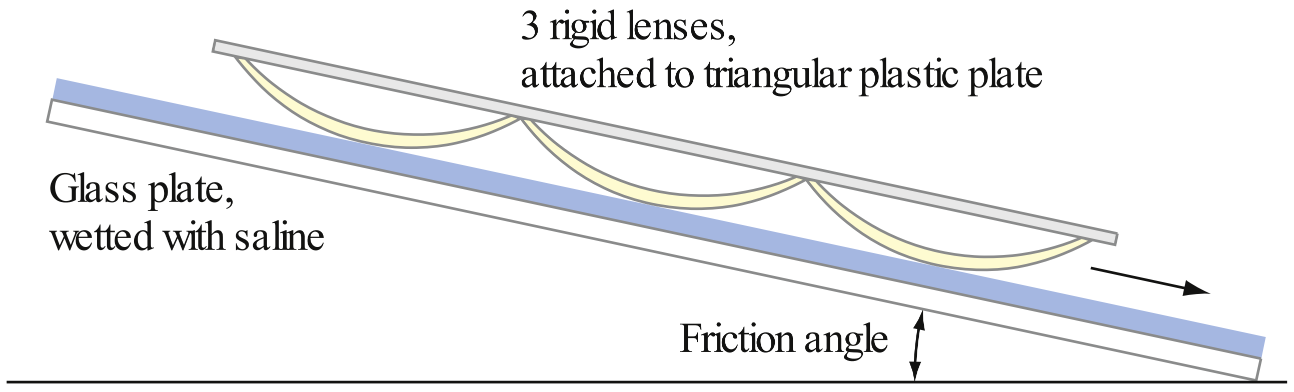


Fig. 14.9 Determining lens friction using the friction angle method.

FRICTION

Friction is a surface and material property that determines how easily two surfaces slide against each other when an external force is applied. Friction is defined as the ratio of the force tangential to the surface to the force normal to the surface. This ratio implies that the friction coefficient is independent of the magnitude of the actual forces and the area of contact. It can however, be significantly affected by the surface texture and the type of lubricant applied between the two surfaces. Static friction applies under conditions for which the two surfaces are at rest and then start moving relative to each other. Kinetic friction is the measured force ratio when one surface moves at a constant speed relative to the other. This coefficient is generally lower than the static friction and applicable to the on-eye condition. The rigid lens is constantly moving relative to the cornea and eyelid.

Attempts have been made to measure friction coefficients in vivo or in vitro using corneal or conjunctival tissues. Although clinically most relevant, the results are generally highly variable and strongly influenced by cofounding and uncontrolled factors (Robinson, 1964; Rennie et al., 2005). A more objective way to determine material specific friction coefficients is to move the lens or a polished button along a glass plate and measure normal and tangential forces.

A very simple procedure to conduct friction measurements in the laboratory or clinical practice utilizes the concept of friction angle. As illustrated in Fig. 14.9, the lens sample is placed on a glass plate, which is then tilted until the sample starts sliding down the plate. The angle against the horizontal is measured and the tangent of that angle represents the static friction coefficient. To measure the kinetic friction, one starts with a steeper angle and pushes the lens downwards. Gradually reducing the angle, a point will be reached at which the lens will stop sliding. The tangent of that angle is the kinetic friction coefficient of that lens material against glass. A suitable lubricant such as saline or artificial tear fluid can be applied to the glass plate to simulate more realistic on-eye conditions. To prevent lenses from tipping over, three lenses of the same material can be attached to a small triangular piece of plastic with double-sided sticky tape and then placed onto the glass plate with the anterior surfaces down.

OXYGEN PERMEABILITY

A comprehensive review of the Dk measurement methods is given in Chapter 7 with respect to soft lens materials. Of the two methods described in ISO 18369-4 (ISO, 2006d), the polarographic one is applicable only to Dk values of up to 145 Barrer, while the coulometric method can be used for all non-hydrogel materials. With a Dk value of around 80–140 Barrer, most modern rigid lens materials can be measured with either method. However, it is known that the two methods can produce different results (Morgan et al., 2001) and specifics of the methodology should accompany any reported Dk values; these include: the method, the particular instrument used and the applied edge and boundary layer corrections.

REFRACTIVE INDEX

The Abbe refractometer is the standard instrument for measuring refractive index of rigid lens materials. This instrument determines the critical incidence angle of a light beam to achieve total internal reflection. The internal reflection is correlated to the refractive index of the optical material. Reliable measurements can be made only if the contact area between the measurement prism and the test material is at least 3 mm^2. The curved surface of rigid contact lenses is difficult to be measured directly, although Hodur et al. (1992) reported that with a drop of saline as contact fluid, reliable readings can be obtained with the hand-held N3000 refractometer (Atago, Japan). More suitable for refractive index measurements are material samples with one flat polished surface.

ISO 18369-4 (ISO, 2006d) specifies that a wavelength of 546 or 588 nm is to be used. The CLR 12-70 refractometer (Index Instruments, UK) is a dedicated instrument for rigid and soft contact lens materials that is fully automated, eliminating operator skills and the subjective variability often reported with manual refractometers.

MODULUS AND FLEXURE

As with the refractive index, the material stiffness cannot be measured using a finished contact lens. The tensile Young's modulus is the most commonly cited stiffness value and can be measured using a general tensile instrument such as the model 5948 MicroTester (Instron, USA). From the material button, a thin strip with a constant and known cross-section needs to be prepared. The strip is clamped on either end and then stretched. From the recorded stress over strain curve, the Young's modulus is determined as the slope of the fitted straight line within the linear region of the material deformation.

Lens flexure is a combined property of material stiffness and lens geometry. It specifically relates to the elastic deformation, which is different from the permanent deformation, usually referred to as lens warpage. Lens flexure is a clinically relevant measure that indicates what deformation it might experience on the eye or how easily a lens might break with handling. ISO 18369-4 (ISO, 2006d) describes in some detail how to perform this measurement. As shown in Fig. 14.10, the lens is clamped at its diameter between two jaws and slowly compressed until the lens breaks while the flexural deformation and force are recorded. Force and deformation at the point of rapture and at 30% of deformation are reported. As this is a destructive test, it is not much use for practitioners.

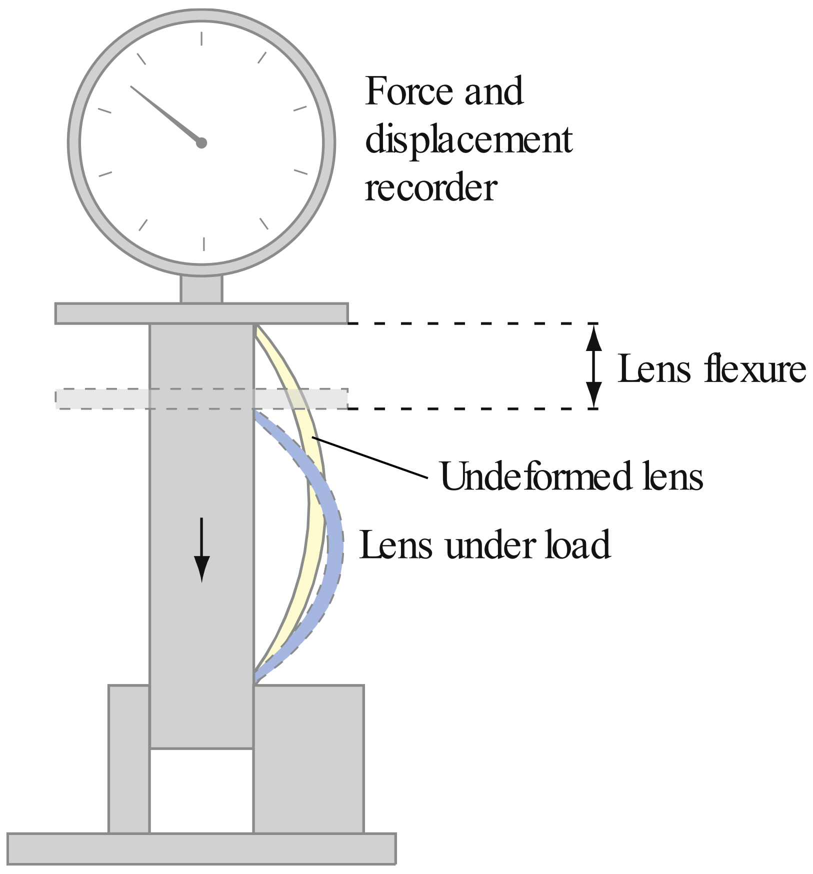


Fig. 14.10 Device to determine flexure of a rigid lens.

Lens laboratories or material manufacturers may be able to obtain some useful information on how thin they can make lenses in a specific material before it becomes too fragile or deforms on eye. Of all the factors that contribute, lens flexure is most sensitive to changes in lens thickness. Thus it is difficult to apply empirically established flexure data to any one particular lens, given the thickness variability with lens powers, manufacturing tolerances for centre thickness and unwanted lens prism (McMonnies, 1989; Ehrmann et al., 1999).

LUMINANCE TRANSMITTANCE

The luminance transmittance of optical materials can be affected by light scattering or absorption, both of which are generally not of concern in rigid materials where transmittance values range from 94% to 97% within the visible spectrum, as specified in the material data sheets from the various manufacturers. Scattering can occur, but in most cases that would be due to surface roughness or scratches. Only rarely can microbubbles or other inclusions be found within the material. Similarly, absorption is generally negligibly small, with the exception where manufacturers deliberately add light-absorbing compounds to the material either to block UV light or to provide a handling tint. In this case, the luminance transmittance needs to be measured with a spectrometer, covering the wavelength range from 200 to 800 nm.

Measurements are best performed using three polished buttons of different thicknesses. By plotting the absorption versus thickness and extrapolation to zero thickness, any surface effects can be eliminated and the actual material absorption obtained. ISO 18369-3 describes a mathematical method to remove surface effects from rigid lens transmissibility measured in air, but this method only partially addressed the issue of surface reflections. Quesnel and Simonet (1995) immersed the rigid lens in saline to minimize surface, power and prism effects and were able to reproduce transmittance curves published by manufacturers. This method can also be used to identify unknown rigid materials, as demonstrated by Dain and Pye (1993).

SURFACE HARDNESS

Hardness is a surface property that describes the resistance against permanent indentation by another body. With respect to rigid contact lenses, it is the key parameter that determines the scratch resistance of a material. Relative scratch resistance can be determined with methods similar to the one described by Tranoudis and Efron (1996), in which they first used an apparatus to scratch one surface of the lens and then applied image analysis tools to quantify the amount of scratching.

Manufacturers usually specify their material hardness in Shore D units. This is measured as the indentation depth of a conical metal tip with a 30° cone angle when a 44.5 N force is applied. Typical values for PMMA are 89 Shore D, with most other gas-permeable materials being up to 30% lower. Surface coatings have been applied to rigid lenses to improve their scratch resistance, but this has the disadvantage that they cannot be repolished and may compromise surface wettability.

Conclusion

Ensuring correct geometrical shape and optical power is critical for clinicians in achieving a successful rigid lens fit. Although manufacturers are obliged to supply only lenses that fall within ISO-allowed tolerances, the contact lens fitter is still advised to scrutinize critical parameters, in particular when patients complain about poor vision or discomfort. Rigid lens tolerances are summarized in Appendix B. Even following successful dispensing, rigid lenses should be regularly inspected throughout their lifetime to check for surface and edge defects as well as lens warping. In most contact lens practices, the required equipment is readily available. For more specialized measurements, the lenses may have to be returned to the lens or material manufacturer. With their dedicated instrumentation, they can fully characterize all aspects related to rigid contact lens design and performance.

Access the complete references list online at http://www.expertconsult.com.

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15

Rigid Lens Design and Fitting

GRAEME YOUNG

Introduction

Fitting rigid lenses is an improbable achievement. Essentially it involves constructing a complex three-dimensional structure to sit, without the aid of any supplementary adhesive, on a vertically inclined surface while being repeatedly dislodged by a covering structure. Fortunately, the task is made easier by a number of mitigating factors:

- The lids help to prevent the lens falling from the eye.
- The change in curvature at the limbal junction helps to prevent sideways drift.
- The capillary forces in the pre-lens tear film are usually strong enough to hold the lens in place but weak enough to avoid adherence.

On the other hand, a number of factors can make rigid lens fitting difficult:

- No two eyes have precisely the same dimensions.
- The worse the refractive error, the less predictable is the fit.
- Reflex tearing during adaptation can alter the lens fit.
- Rigid lenses can be very uncomfortable, no matter how good the fit.

The fit of a rigid lens is affected by a range of factors, many of which are not easily quantifiable, such as corneal and limbal anatomy, lid geometry and mechanics, and extraneous factors such as pterygia. As a result, many practitioners consider rigid lens fitting to be more of a craft than a science. There is, therefore, a wide variation in competence between practitioners, which primarily relates to experience. Practitioners new to rigid lens fitting can benefit greatly in the initial stages from being overseen by a more experienced colleague.

Ocular Topography

A number of ocular dimensions are relevant to the selection of rigid lenses. These are summarized in Table 15.1, along with typical population variations. Precise measurement of each of these dimensions is not essential to successful rigid lens fitting; however, for a given patient, it is helpful to assess whether the eye is close to average or atypical, for instance, whether the corneal diameter is larger or smaller than average.

CORNEA

The cornea is generally aspheric in shape and is frequently described as ellipsoid (Kiely et al., 1982). In most cases, a corneal section can be approximated to a prolate ellipse – that is, one that gradually flattens towards the periphery. Conventional keratometers give readings corresponding to points approximately 1.5 mm either side of the corneal apex. Given that corneas with similar keratometer readings (K-readings) can show widely differing peripheral curvature (asphericity), keratometry alone does not always indicate the optimum rigid lens fit.

The degree of corneal asphericity is often expressed as either corneal eccentricity or corneal shape factor. With eccentricity (e) a spherical surface equals zero, while a flattening ellipse equates to a positive value. Shape factor (SF) is a function of eccentricity, whereby:

$$SF = 1 - e^2$$

Using shape factor, a spherical surface equals 1.0, a flattening ellipse is <1.0, while a steepening ellipse is >1.0.

With-the-rule astigmatic corneas are steeper in the vertical meridian and are generally easier to fit than against-the-rule astigmatic corneas, on which rigid lenses tend to show sideways decentration. With-the-rule astigmatic corneas often show greater corneal astigmatism in the inferior cornea compared with the superior cornea. As a rule of thumb, 1.00 D of corneal astigmatism corresponds to a difference in K-readings of approximately 0.2 mm. The peripheral cornea tends to show less toricity than does the central cornea (Read et al., 2006).

There is no correlation in the population between corneal asphericity and central corneal curvature (Guillon et al., 1986; Hall et al., 2013). However, there is a correlation between K-readings and corneal diameter such that larger corneas tend to be flatter in curvature whereas smaller corneas tend to be steeper (Mandell, 1989). Also, there is a correlation between asphericity and the degree of myopia; higher myopes show less peripheral corneal flattening, which is consistent with the longer axial length of the myopic eye (Carney et al., 1997a).

The cornea is invariably larger in the horizontal meridian than in the vertical. It is not easy to measure the true diameter of the cornea owing to the gradual change in transparency at the limbus. In practice, the width of the visible iris (horizontal visible iris diameter, HVID) is used as a gauge of corneal diameter. The HVID is approximately 1.5 mm smaller than the actual corneal diameter (Martin and Holden, 1982; Hall et al., 2013).

TABLE 15.1 Ocular Dimensions and Typical Population Variations

	Mean (mm)	±2 SD (mm)
Flattest corneal curvature – keratometry	7.85	7.25–8.45
Corneal shape factor	0.67	0.40–0.95
Corneal diameter	13.3	11.7–14.1
Horizontal visible iris diameter	11.7	10.7–12.7
Palpebral aperture	10.2	7.4–13.0

SD = standard deviation.

(Data from Hall, L., Hunt, C., Young, G. & Wolffsohn, J. (2013). Factors affecting corneoscleral topography. Invest. Ophthalmol. Vis. Sci., 54, 3691–3701.)

Corneal diameter influences the choice of lens diameter. The typical variation in corneal diameter of 2.4 mm (see Table 15.1) is mirrored by a similar variation in typical rigid lens diameter, that is, 8.30–9.80 mm.

LIDS

The lower lid usually aligns with the lower limbus while the upper lid tends to cover the limbus and overlap by approximately 1 mm. Both of the eyelids can help to position the lens high enough to cover the pupil and, in many cases, the lens is effectively passed from one lid to the other between blinks.

The maximum vertical distance between the lids (palpebral aperture) is generally measured prior to fitting. Smaller palpebral apertures tend to require smaller-diameter lenses; however, the relationship of the lids to the superior and inferior limbus is also relevant, and therefore there is no simple relationship between palpebral aperture and optimum lens diameter. Rigid lens wear itself can cause a reduction in palpebral aperture. Fonn et al. (1996) noted that the palpebral aperture in rigid lens wearers is, on average, 0.5 mm smaller than that in soft lens wearers.

When the upper lid is relatively high, the lens tends to decentre low and a large-diameter lens is often required to encourage the upper lid to grip the lens and hold it in place; this is known as lid attachment. A relatively low upper lid and narrow palpebral aperture tends to result in upwards decentration (Carney et al., 1997b).

In cases where the lower lid is positioned higher than the limbus, a smaller lens may be required. On the other hand, when the lower lid is low or ineffective owing to ectropion, a large-diameter lens is often required, again to encourage lid attachment.

There is a correlation between palpebral aperture and corneal diameter. Larger corneas, as well as being relatively flat, tend to be accompanied by a wider palpebral aperture.

ETHNIC VARIATIONS IN OCULAR DIMENSIONS

Some ethnic variations in ocular topography have been noted in the literature. In a UK-resident Chinese population, corneas have been noted to be steeper and smaller and to show less corneal flattening than Caucasian eyes (Lam and Loran, 1991). This suggests a requirement for smaller rigid lenses showing less peripheral flattening for such patients. In a more recent study, however, Chinese and Japanese corneas tended to be slightly flatter but to show similar asphericity in the flatter meridian (Hickson-Curran et al., 2014). It is likely that environmental factors, such as nutrition, as well as ethnic differences influence corneal topography and probably account for the mean flattening in corneal curvature noted in the Japanese population over a 20-year period (Hirotsuji, 1990). As expected, oriental eyes tend to show a narrower palpebral aperture: on average, about 1.0 mm smaller than Caucasian eyes (Lam and Loran, 1991; Hickson-Curran et al., 2014). A comparison of Caucasian and British Asian eyes noted smaller corneas in the British Asian population but no difference in curvature or asphericity (Hall et al., 2011).

There is less information on ethnic variations in Afro-Caribbean populations, although there is some evidence that these corneas tend to be larger and flatter than corneas of Chinese or Japanese populations (Babalola and Szajnicht, 1960). One study noted that African-American corneas tended to be more prolate than in Caucasians (Fuller and Alperin, 2013).

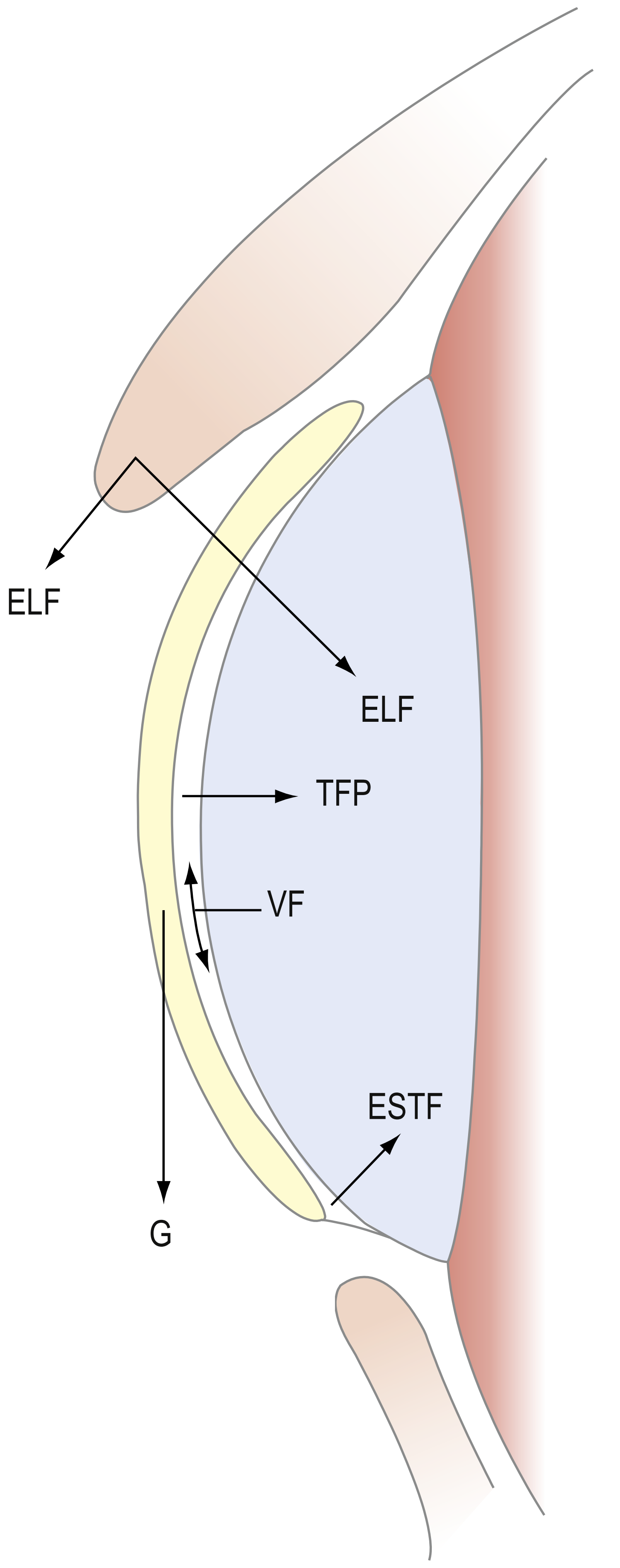


Fig. 15.1 Forces acting on a lid-attached rigid lens. ELF = eyelid force; ESTF = edge surface tension force; G = gravity, TFP = tear fluid pressure; VF = viscous forces. (Adapted from Guillon, M. & Sammons, W. A. (1994) Contact lens design. In M. Ruben & M. G. Guillon (eds) Contact Lens Practice (Ch. 5, pp. 87–112). London: Chapman & Hall.)

Forces Acting on the Rigid Lens

A number of forces act on the rigid lens and have to be suitably balanced in order to achieve a satisfactory fit (Fig. 15.1). The gravitational force of the lens and pre-lens tear film cause the lens to drop. The effect will be greater, and the lens less stable, the further forwards the centre of gravity lies. The centre of gravity is further forward in plus lenses compared with minus lenses (Fig. 15.2). It is shifted posteriorly by increasing the diameter, steepening the back optic zone radius (BOZR), or decreasing the thickness of the lens. With both plus and minus lenses, the greatest shift and most effective stabilization are achieved through changing the lens diameter (Carney and Hill, 1987).

The lens is held in place by the capillary forces in the post-lens tear film and the surface tensional force in the tear meniscus at the lens edge. The capillary force increases with increasingly closer alignment of the lens and the cornea. The force is therefore greater with spherical corneas compared with astigmatic corneas. Fig. 15.3 shows the change in apparent alignment with increasing astigmatism.

Surface tension forces act at the lens edge where the edge meniscus is not covered by the lid. There will be no surface tension where a meniscus is absent owing to excessive edge clearance. This force can be increased by reducing edge clearance and edge thickness (Khorassani and Peterson, 1988).

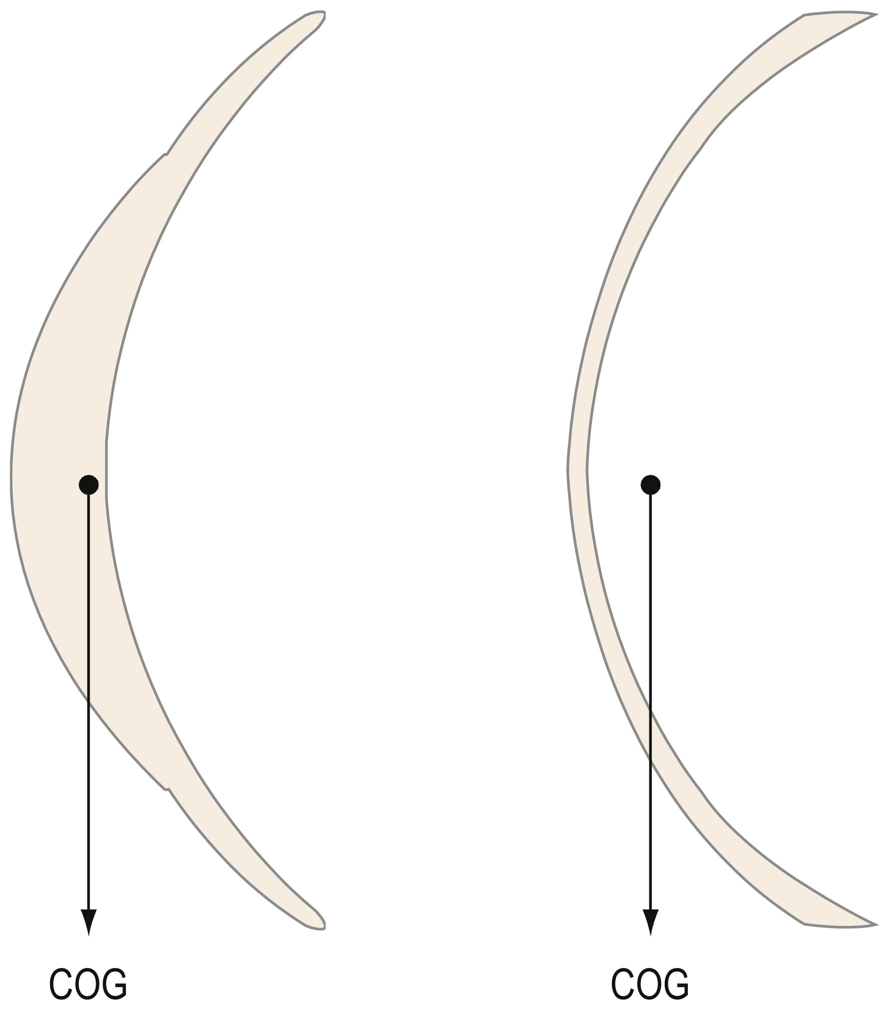


Fig. 15.2 Rigid lens centre of gravity (COG) in a plus (left) and minus (right) power lens.

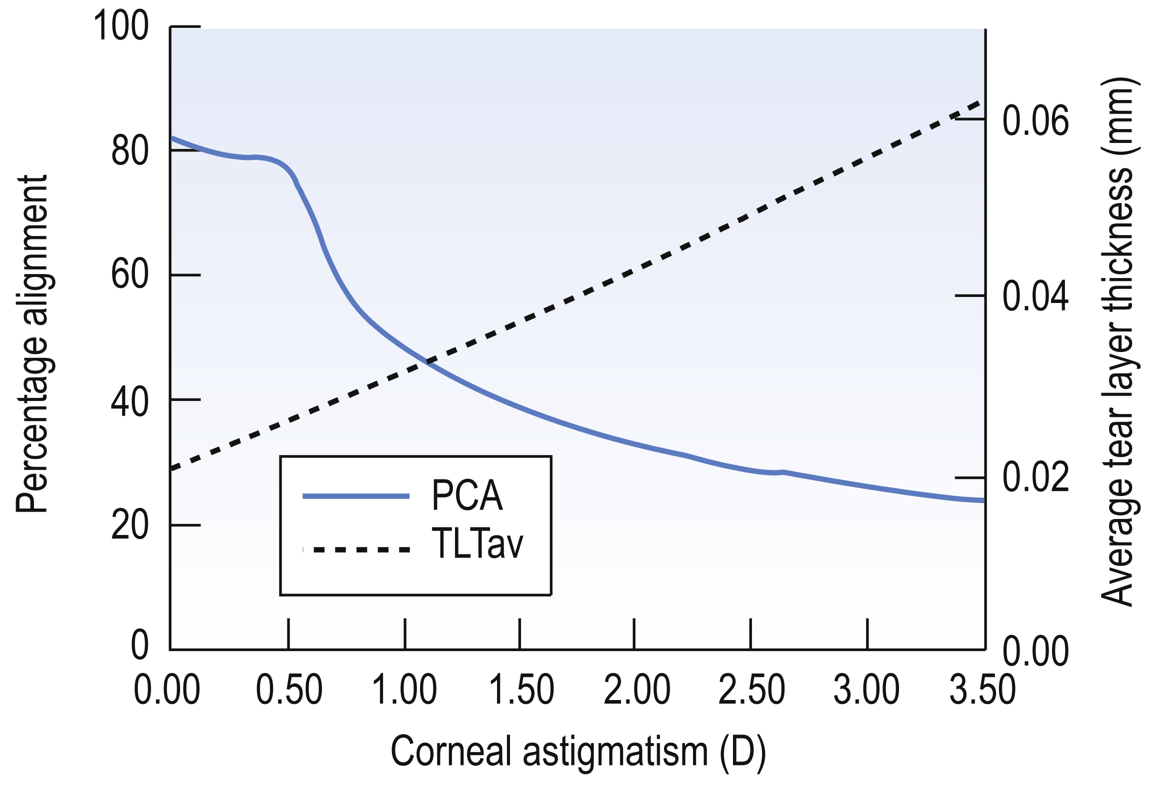


Fig. 15.3 Apparent percentage corneal alignment (PCA) and average tear layer thickness (TLTav) with increasing corneal astigmatism.

Eyelid forces (primarily the upper lid) act to move the lens in a vertical direction during the blink. Between blinks, these forces help to stabilize the lens in the case of a lid attachment fit but have no effect in the case of an interpalpebral fit.

Rigid Lens Design

BACK OPTIC ZONE DIAMETER

The back optic zone diameter (BOZD) is usually fixed for a given design in a given total diameter (TD) and is generally 1–1.5 mm smaller than the TD. The BOZD should be large enough to cover the pupil in most conditions, including low illumination.

With toroidal corneas, using a smaller BOZD can increase the area of alignment and therefore improve the fit. However, if the BOZD is reduced while maintaining the same TD, this results in a wider periphery and flatter peripheral curves are required in order to maintain edge clearance.

If the BOZD is changed, it is usually necessary to change the BOZR in order to maintain a clinically equivalent fit. Reducing the BOZD without reducing the BOZR results in a sagittal depth that is shallower and therefore a flatter fit. As a rule of thumb, an increase in BOZD of 0.5 mm requires an increase in BOZR of 0.05 mm.

TABLE 15.2 Suggested Centre Thicknesses

Lens Power (D)	Centre Thickness (mm)
−1.00	0.18
−2.00	0.17
−3.00	0.16
−4.00	0.15
≥−5.00	0.14

Add 0.02 mm for corneal astigmatism ≥2.00 D.

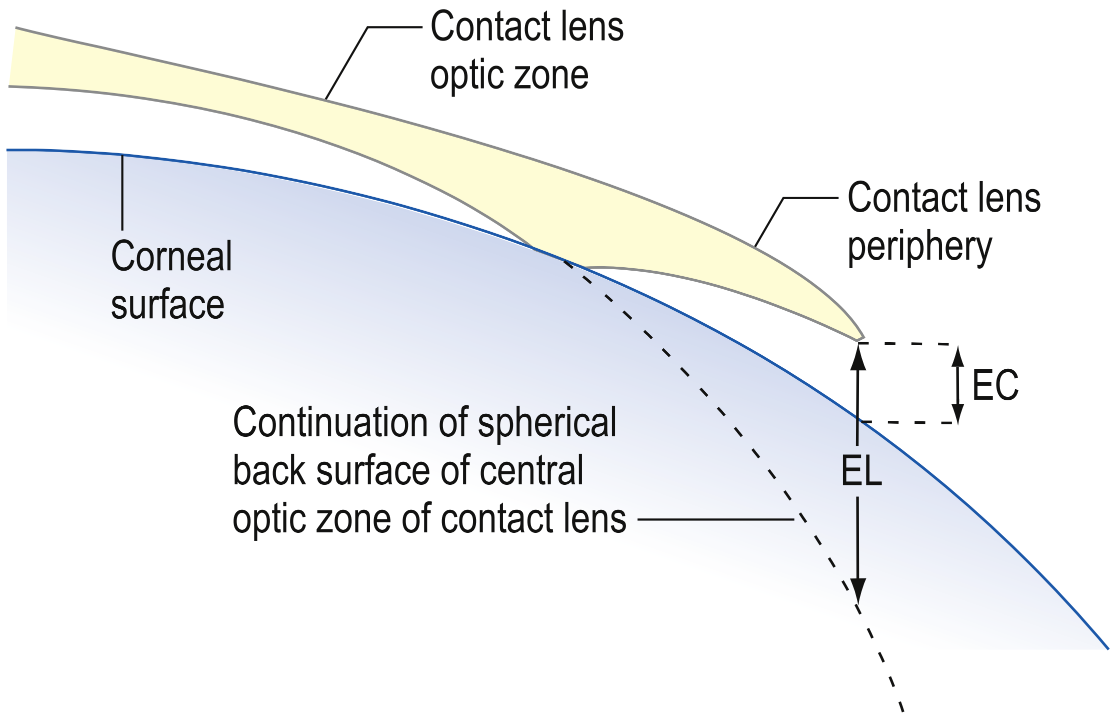


Fig. 15.4 Axial edge lift (EL) and edge clearance (EC).

FRONT OPTIC ZONE DIAMETER

The front optic zone diameter (FOZD) should be at least 0.5 mm larger than the BOZD. Except in low powers, most rigid lenses are lenticulated so as to reduce thickness and weight.

Lenses occasionally incorporate a negative carrier in order to encourage lid attachment and to centre the lens. A negative carrier is a peripheral zone that is thinner at the optic zone junction than at the lens periphery. A positive carrier or tapered-edge design – where the peripheral zone is thicker at the optic zone junction than the lens periphery – is occasionally used to discourage lid attachment in a high-riding lens.

CENTRE THICKNESS

If lenses are made too thin, not only is there a greater risk of breakage but also the lenses tend to flex on astigmatic corneas, leaving residual astigmatism. As flexure is a function of lens thickness, it is worse with low-minus-powered lenses. For a given family of materials, flexure tends to increase with increasing Dk. It is therefore necessary to increase lens centre thickness with higher-Dk materials. Table 15.2 gives suggested centre thickness values for lenses of varying power.

EDGE LIFT AND EDGE CLEARANCE

Without a peripheral gap between the edge of the lens and the cornea, mechanical pressure leads to superficial corneal damage. Such a gap is also important for tear exchange and to enable lens removal using the lids. This gap is termed the edge clearance and can be specified axially or radially. A minimum axial edge clearance of 60–80 µm when the lens is centred is considered to be the optimal value (Atkinson, 1984).

Whereas edge clearance relates to the lens and cornea, edge lift relates to the lens only (Fig. 15.4).

Some rigid lens designs follow a concept of constant edge lift throughout the range of BOZRs; however, this tends to result in greater edge clearance at the flatter end of the range. A superior design is one that gives constant edge clearance for corneas of similar asphericity. Constant edge clearance designs based on those proposed by Guillon et al. (1983) are given in Appendix H.

EDGE FORM

The shape of the lens edge is one of the most important factors in minimizing any discomfort. Poor edge rounding, in particular, can result in greater edge awareness by the upper eyelid. Good rounding of the front surface edge has been shown to be more important than rounding of the posterior edge (La Hood, 1988). This suggests that the interaction of the edge of the lens with the eyelid is more important in relation to comfort than the interaction with the cornea. Fig. 15.5 shows examples of edge shapes.

SPHERICAL VERSUS ASPHERIC DESIGNS

A wide variety of surface shapes have been used in rigid lenses. These can be broadly categorized as: spherical, aspheric or a combination of the two (e.g. spherical centre with aspheric periphery). An aspheric back surface design is theoretically capable of providing better alignment to the cornea (which is aspheric), although there are a number of advantages and disadvantages to both types (Table 15.3).

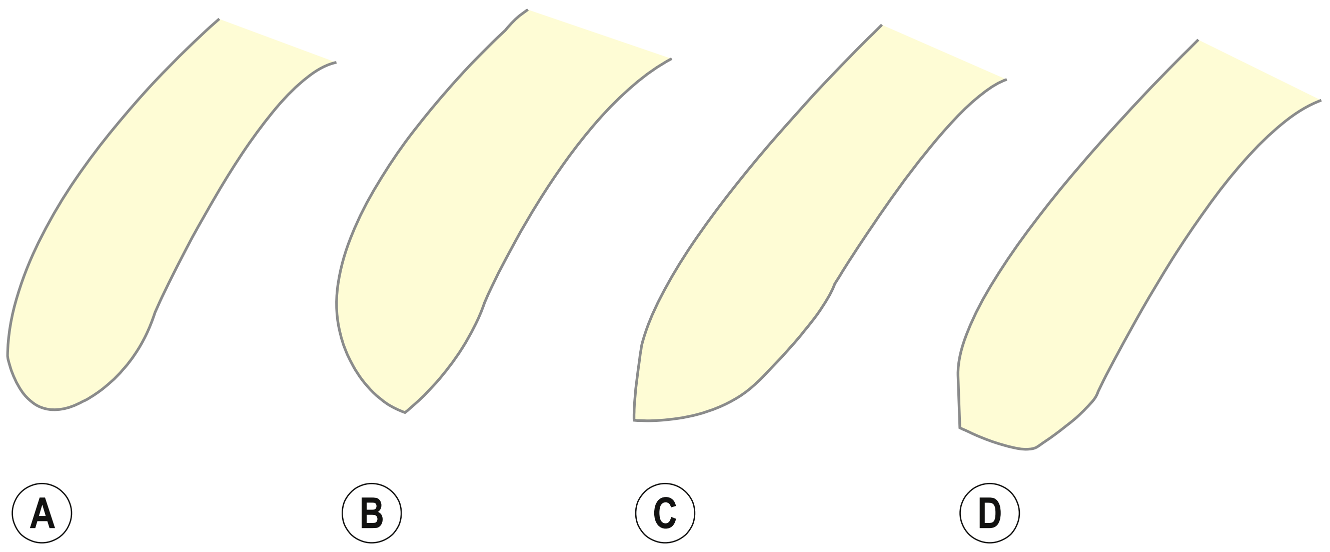


Fig. 15.5 Rigid lens cross-sections showing variations in edge form. (A) Well-rounded edge; (B) sharp posterior edge; (C) sharp anterior edge; (D) flat edge.

SPHERICAL DESIGNS

Spherical designs incorporating a spherical back optic zone with a number of flatter spherical peripheral zones are the most widely used and readily understood form of rigid lens. The peripheral zone is generally 1–2 mm in width and composed of one to four peripheral curves. Tricurve designs (i.e. a central curve plus two peripheral zones) are probably the most commonly used lens form. Bicurve designs are occasionally used with small lenses (e.g. <8.5 mm). Tetracurve and other multicurve designs are used with larger lenses or where a smoother transition is required between the peripheral zones.

The front surfaces of most spherical designs are bicurve, incorporating an optic zone that is slightly larger than the BOZD and a front-surface peripheral zone. The curvature of the optic zone is governed by the required lens power and that of the peripheral zone governed by the edge thickness, the power and FOZD of the lens; these parameters are invariably calculated by the manufacturing laboratory. Monocurve front-surface designs (single-cut) are occasionally used in small, low-power lenses but most lenses are lenticulated (i.e. made with a thinner peripheral zone) in order to reduce mass and overall thickness. Multicurve front-surface designs are occasionally used with higher-power lenses in order to reduce peripheral thickness.

ASPHERIC DESIGNS

From a mathematical point of view, the choice of spherical geometry is almost arbitrary as the sphere is merely one of an infinite number of conic sections. As noted earlier, few if any corneas are spherical in shape and therefore a spherical back surface is not the obvious choice. However, aspheric rigid lenses have two important disadvantages compared with spherical lenses: (1) they are more difficult to manufacture, particularly using conventional lathes; and (2) they cannot easily be checked using a radiuscope or keratometer. Nevertheless, they offer a number of advantages that arguably outweigh their disadvantages (see Table 15.3).

The main advantages of aspheric designs relate to comfort. Aspheric designs tend to show less edge clearance and therefore induce less edge sensation from contact with the palpebral conjunctiva. Poor blending of back-surface junctions in spherical lenses can cause irritation on version when the lens moves

TABLE 15.3 Advantages and Disadvantages of Aspheric versus Spherical Rigid Lenses

	Spherical	Aspheric
Manufacture	Relatively easy	Easy with computer-controlled lathes Not easy with conventional lathes
Verification	Easy	Difficult
Induced Astigmatism	None	Small amount with decentration
Presbyopic Correction	None	Small amount
Corneal Alignment	Adequate	Slightly greater
Edge Clearance	Usually 80–120 µm	Usually 60–90 µm
Back Surface Junctions	Can be a problem if not blended	Rarely a problem
Thickness	Can be minimized by lens design	Thinner periphery possible
Comfort	Slight to moderate discomfort	Sometimes better owing to reduced thickness and edge clearance

off-centre and the peripheral zones come into contact with the cornea. This is generally avoided with aspheric lenses unless the periphery is poorly blended. The gradual flattening of aspheric lens surfaces results in a thinner periphery, which may also help reduce edge sensation.

Optically, aspheric designs can both improve and degrade image quality. When not aligned with the visual axis, aspheric lenses will induce astigmatism. On the other hand, with higher-power lenses, aspheric optics can reduce spherical aberration. In myopic early presbyopes, the reduced minus power in the periphery of aspheric lenses can help with near vision and delay the need for a presbyopic correction.

Aspheric designs take different forms but these differences are usually too subtle to be evident other than from the product literature of the manufacturer. The simplest aspheric design is an elliptical shape selected to be close to, or slightly flatter than, the average cornea. More complex aspheric designs change their degree of flattening (or eccentricity) from centre to edge. Some designs are spherical in the centre, changing to aspheric geometry towards the periphery. Most aspheric designs incorporate a much flatter, often spherical, peripheral zone about 0.2 mm wide. This peripheral zone serves to avoid mechanical irritation when the lens decentres to the peripheral cornea.

PMMA VERSUS RGP LENS DESIGN

Given the risk of corneal exhaustion syndrome and other chronic hypoxic effects of the cornea, there is little or no justification for fitting polymethyl methacrylate (PMMA) lenses (Sweeney, 1992). However, it is useful to have an appreciation of differences in design between non-gas-permeable PMMA lenses and rigid gas-permeable (RGP) lenses so that, when PMMA lenses are being refitted, these differences can be taken into account. Because of the reliance on transfer of oxygen through the tears to the post-lens cornea, PMMA lens designs generally incorporate a wider and flatter periphery. This results in a narrower optic zone and greater edge clearance (Khorassani and Peterson, 1988). In comparison, RGP lens designs usually incorporate the following features:

- larger TD
- larger BOZD
- narrower periphery
- steeper peripheral curves (resulting in less edge clearance).

Trial Fitting Options

The traditional method of fitting rigid lenses is by way of reusable trial lenses, although other options such as empirical fitting have become increasingly popular. With the theoretical risk of transmission of infection by contact lenses, the use of trial lenses has been questioned, although Hogan (2003) showed the chance of obtaining prion disease through contact lens use to be negligible.

TRIAL FITTING SET

The use of trial lens (or diagnostic) fitting sets in a range of BOZRs and TDs was once the standard method for fitting rigid lenses.

A set of lenses in a given trial fitting set generally follows a single design concept – for instance, constant edge clearance. Lenses in a standard trial fitting set are typically available in a single diameter and back vertex power (BVP) with a range of BOZRs in 0.1 mm steps; however, it is preferable to use fitting sets that have lenses available in two diameters (e.g. 9.2 and 9.8 mm). Examples of additional useful fitting sets include:

- plus power, e.g. +3.00 D, smaller diameter
- high minus, e.g. −8.00 D, larger diameter
- small diameter for interpalpebral fitting, e.g. 8.6 mm
- keratoconic, diameter varying with BOZR.

Sodium hypochlorite (Milton) in 20 000 ppm solution has been suggested as an effective method of disinfecting rigid trial lenses.

EMPIRICAL FITTING

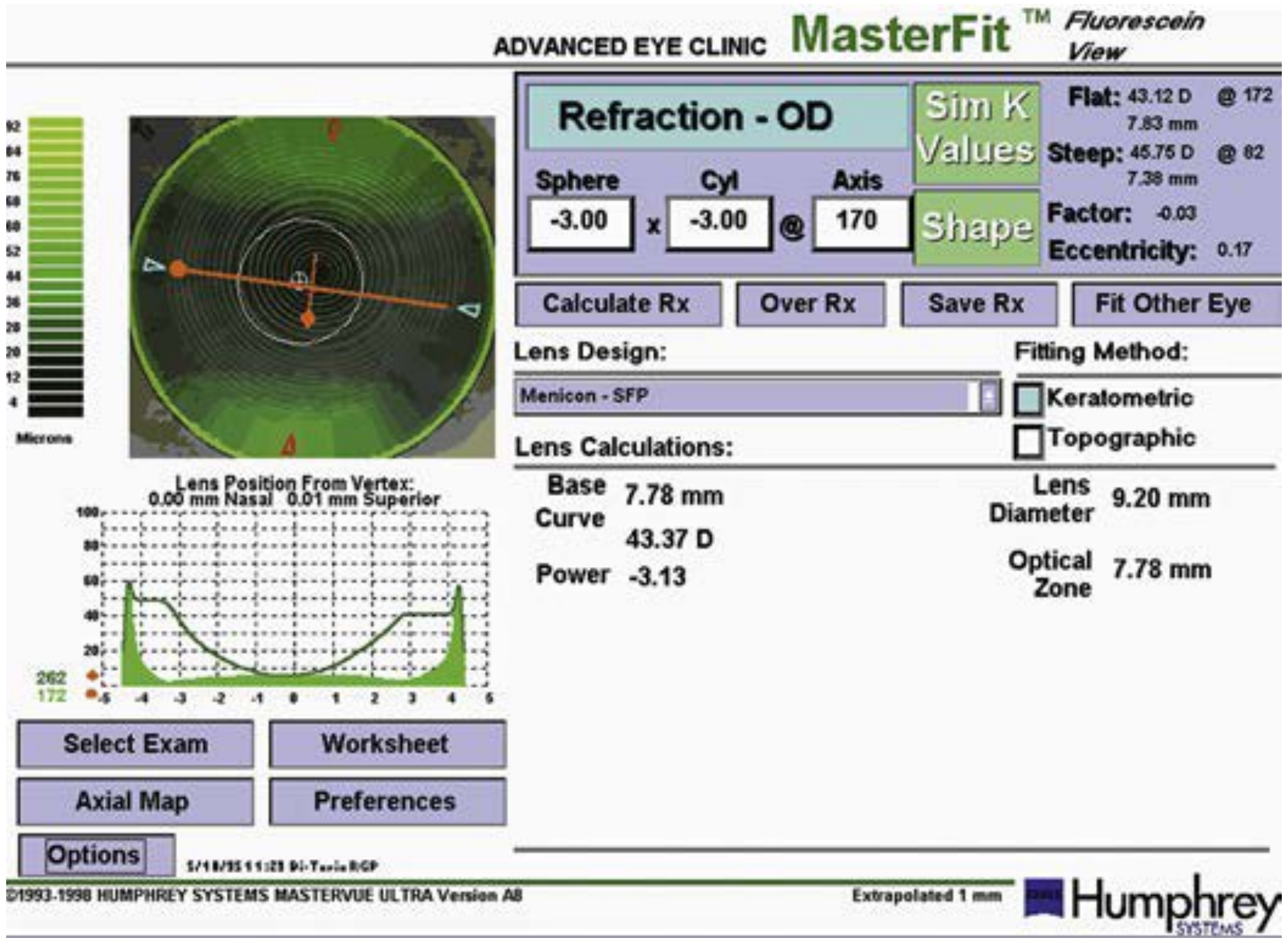
A high degree of success can be achieved by empirical fitting (i.e. ordering initial lenses based on keratometry and refraction). In one study, 91% of eyes were successfully fitted by this method (Back et al., 1996).

Most contact lens laboratories will supply lenses on a per-case basis – that is, a fixed cost for an unlimited number of lens exchanges for a given patient until a final satisfactory fit is obtained. This is an attractive option, especially in avoiding concerns about cross-infection. Furthermore, there are occasions when this method is the only practical method, for example when wishing to fit a design not covered by available fitting sets or when an initial trial fitting is simply not convenient for the patient.

CORNEAL TOPOGRAPHY (VIDEOKERATOSCOPY) FITTING

Most corneal topographers incorporate rigid lens fitting software (Fig. 15.6). This enables practitioners to model different rigid lenses designs on an accurate representation of the cornea of the patient (Caroline et al., 1994). The fitting success rates are relatively low when relying solely on using the default settings of the corneal topographer but can be relatively high (77–93%) when an experienced practitioner uses the software to select an appropriate lens (Jani and Szczotka, 2000).

Most corneal topographers use a Placido disc image reflected from the cornea, which is automatically measured and interpreted to produce corneal topography maps or videokeratograms. These maps can be presented as corneal curvature maps or corneal elevation maps. From the point of view of rigid lens fitting, elevation maps are the most useful. Conventionally,



Refraction - OD
Sphere -3.00 x Cyl -3.00 @ Axis 170
Flat: 43.12 D @ 172 7.83 mm
Steep: 45.75 D @ 82 7.38 mm
Factor: -0.03
Eccentricity: 0.17
Lens Design: Menicon - SFP
Fitting Method: ☒ Keratometric ☐ Topographic
Lens Calculations:
Base Curve 7.78 mm 43.37 D
Power -3.13
Lens Diameter 9.20 mm
Optical Zone 7.78 mm
Lens Position From Vertex: 0.00 mm Nasal 0.01 mm Superior

Fig. 15.6 An example of videokeratoscope rigid lens fitting software.

TABLE 15.4 Guidelines for the Initial Selection of a Rigid Lens

A. SELECTION OF LENS TOTAL DIAMETER

HVID (mm)	Small PA <9.5 mm	Average >10.7 mm	Large PA
<11.2	8.2	8.6	9.2
11.2–11.6	8.6	9.2	9.6
11.6–12.0	9.2	9.6	10.0
>12.0	9.6	10.0	10.0

B. SELECTION OF LENS BACK OPTICAL ZONE RADIUS (BOZR)

Lens Diameter (mm)	BOZR (mm)	BVP (D)
8.2	K−0.05	S
8.6	K−0.05	S−0.25*
9.2	K−0.05	S−0.25*
9.6	K−0.05	S−0.25*
10.0	K	S

HVID = horizontal visible iris diameter; PA = palpebral aperture; BVP = back vertex power; K = flattest K-reading; S = vertex-corrected sphere from minus-cylinder spectacle prescription.

*Add −0.25D.

steeper parts of the cornea are presented as 'hotter' colours such as red and orange (see Chapter 41). With-the-rule astigmatism corneal maps show a vertically oriented 'bow-tie' pattern. Keratoconic corneas show a rapid change in colour (or curvature) near the corneal apex.

The main advantages of corneal topographer elevation maps in rigid lens fitting are that they:

- indicate whether the corneal apex is decentred
- show atypical corneal shapes, e.g. extremes of corneal asphericity
- allow the practitioner to monitor changes in corneal shape
- allow virtual trial fitting of rigid lenses.

There is an apparent trend for rigid lens fitting to be used more for specialist fits (Morgan and Efron, 2008), in which case elevation maps are likely to prove increasingly useful. The obvious limitation of elevation maps in trial lens fitting is that they fail to take into account the influence of the lids.

Selection of Initial Lenses

TRIAL FITTING SET

The procedure for selecting an initial fitting of spherical lenses using a trial fitting set is as follows:

1. Select a lens diameter based on corneal diameter, palpebral aperture and lid configuration (Table 15.4).
2. Select the BOZR based on flattest keratometer (K) reading, adjusting the BOZR to be flatter or steeper than K depending on BOZD. Since relatively steep-fitting lenses are easier to visualize with fluorescein, err on the steep side.
3. If more than one power is available, select a lens power closest to the refraction of the patient.

EMPIRICAL FITTING

The procedure for empirical fitting of spherical lenses is as follows:

1. Select a lens diameter based on corneal diameter, palpebral aperture and lid configuration (see Table 15.4).
2. Select the BOZR based on flattest K-reading (K), adjusting the BOZR to be flatter or steeper than K depending on BOZD. Flatter radii tend to be used with larger BOZD and vice versa.
3. If the lens is an average diameter, select the BVP based on the sphere power from the refraction (minus cylinder form) corrected for vertex distance. With an average-diameter lens, no adjustment is necessary; however, an adjustment is necessary if the BOZR is steeper or flatter than K.
4. Order the lens and use this effectively as a trial fitting lens, being prepared to modify or reorder before dispensing.

Lens Insertion, Removal and Settling

LENS INSERTION

Whether the initial lens is selected empirically, by corneal topographer or from a trial fitting set, it is necessary to assess the lens on the eye. With experienced rigid lens wearers, having the patient insert the lens enables the practitioner to assess the patient's technique. Some patients fall into bad habits such as licking lenses or inserting them on to the sclera. With new patients, it is preferable for the practitioner to insert the lenses rather than adding to the patient's anxiety.

Before inserting the first lens in new wearers, it is helpful to prepare the patient for some initial discomfort, to advise that this will recede and to suggest that any discomfort will be minimized by looking downwards. Anxiety may also be reduced by explaining that any discomfort will be to the eyelid rather than the eye itself, which will be unaffected. Applying wetting solution to the lens before insertion will tend to make the lens more comfortable and transfer more readily to the eye, but avoid applying more than a small drop as too much can make fluorescein assessment more difficult.

To minimize initial discomfort in new wearers the use of a topical anaesthetic has been advocated. By reducing reflex lacrimation it is possible that a more accurate assessment of lens fit may be made. Although controversial, Bennett et al. (1998) showed that the use of a topical anaesthetic at the fitting and dispensing visits for first-time wearers of rigid lenses resulted in significantly fewer dropouts, improved initial comfort and gave an enhanced perception of the adaptation process and greater overall satisfaction after 1 month of lens wear.

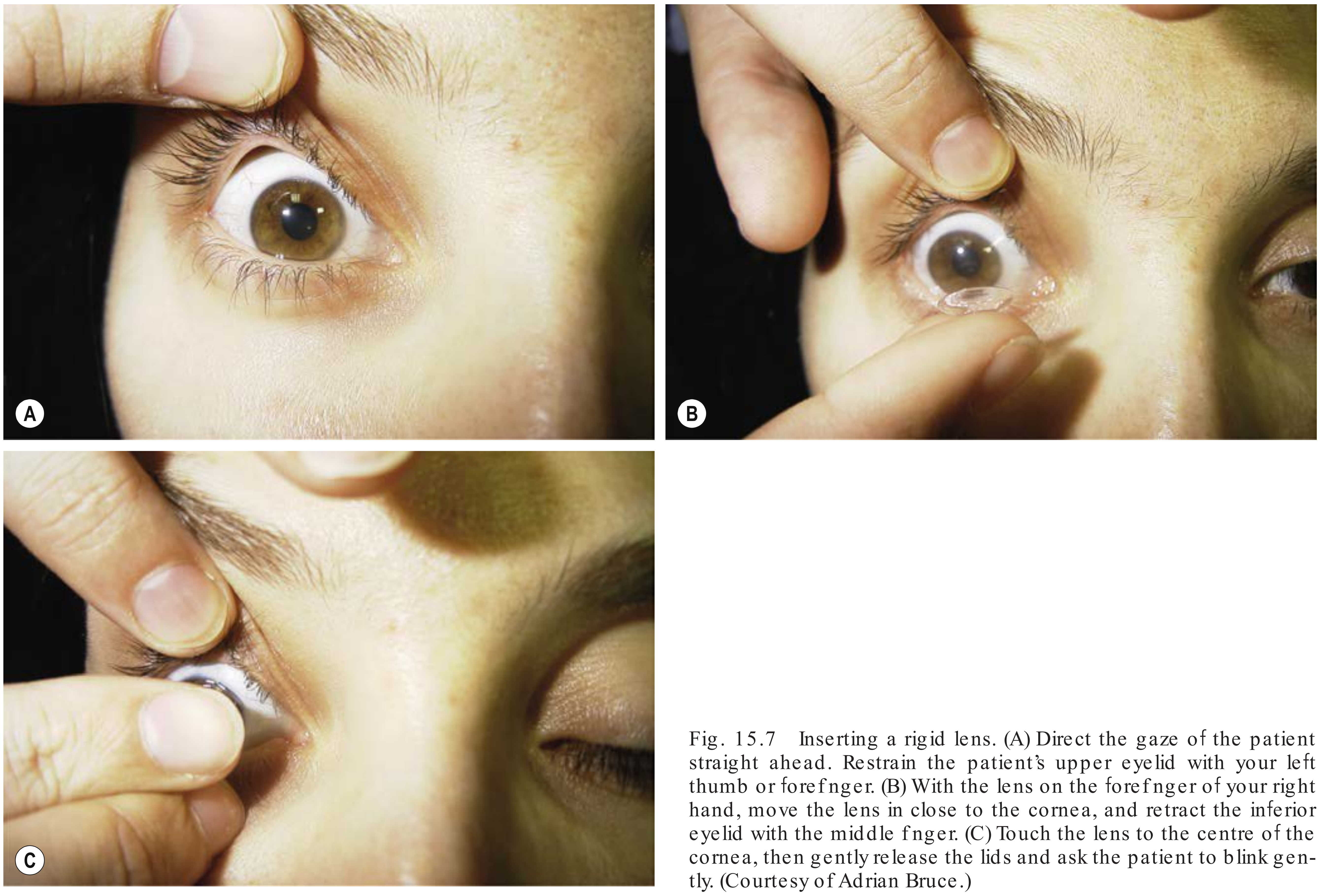


Fig. 15.7 Inserting a rigid lens. (A) Direct the gaze of the patient straight ahead. Restrain the patient's upper eyelid with your left thumb or forefinger. (B) With the lens on the forefinger of your right hand, move the lens in close to the cornea, and retract the inferior eyelid with the middle finger. (C) Touch the lens to the centre of the cornea, then gently release the lids and ask the patient to blink gently. (Courtesy of Adrian Bruce.)

To insert a rigid lens:

1. Ask the patient to fixate a distant object to steady the eyes.
2. Place the lens on the index finger of the hand that will be holding the patient's bottom lid.
3. Hold the patient's top lid using the index finger or thumb of the other hand (Fig. 15.7A). If this proves difficult, have the patient first look down until the lid is securely held.
4. Hold the bottom lid using the middle finger of the hand holding the lens (Fig. 15.7B) and place the lens directly onto the centre of the cornea (Fig. 15.7C).
5. Release the bottom lid but continue to hold the top lid and ask the patient to look down.
6. At this point, the lens is often quite comfortable. Warn the patient that once you let go of the lid, the patient will be more aware of the lens.

If the lens locates onto the sclera, the lens will probably not be uncomfortable. Have the patient look in the opposite direction to where the lens is located (e.g. upwards if the lens is located on the lower sclera). With two fingers, manipulate the lens towards the cornea using the lids (Fig. 15.8). If this proves difficult, remove the lens using the patient's lids or a suction holder.

LENS REMOVAL

To remove a rigid lens:

1. Place the index fingers of each hand on the lids of the patient above and below the centre of the lens (Fig. 15.9A).
2. If necessary pull the lids apart in order to position the lid margins at the lens edges.
3. Gently press the eyelid margins on to the eye and towards each other (Fig. 15.9B).
4. The lens may then be grasped and removed (Fig. 15.9C).

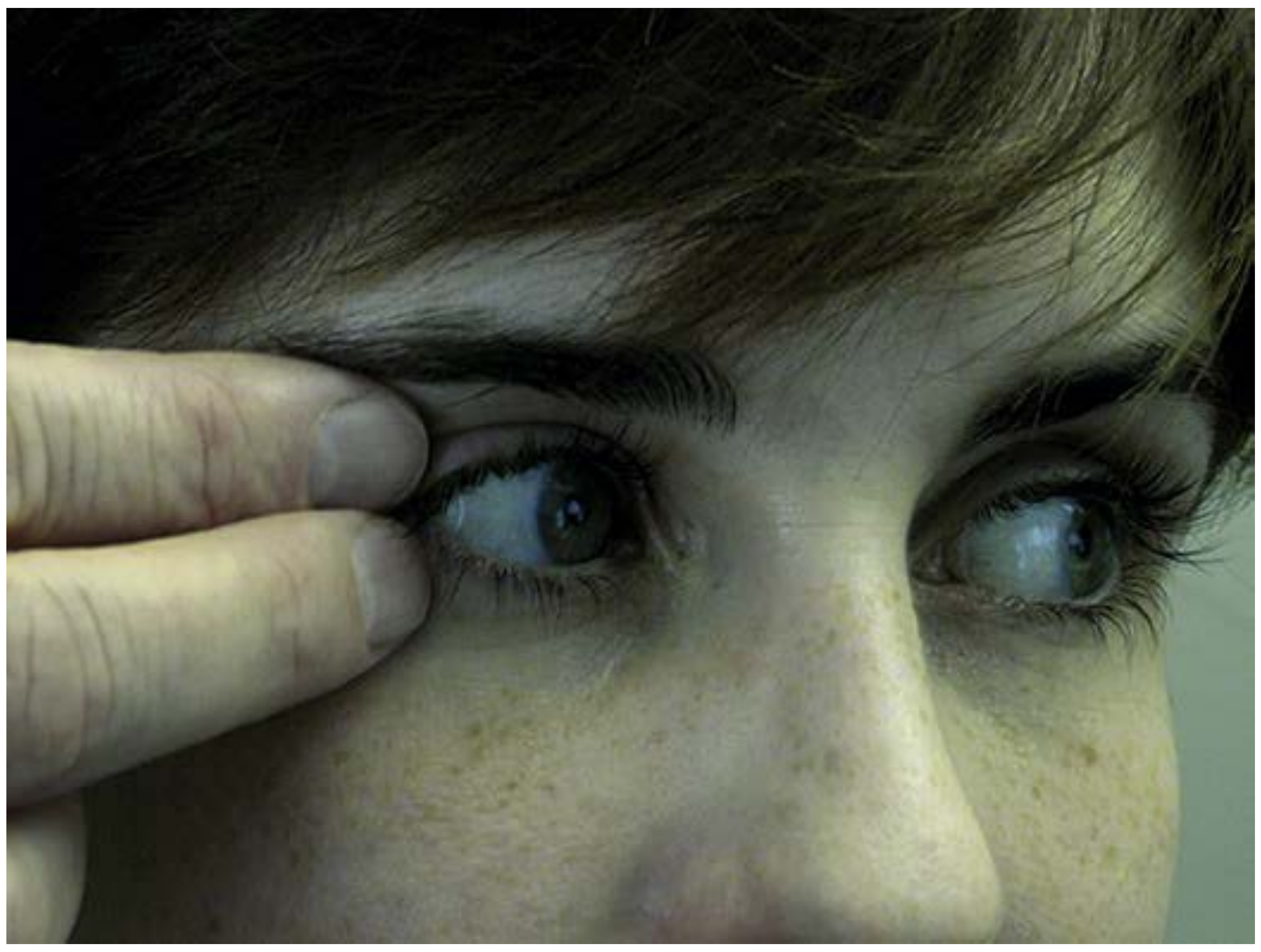


Fig. 15.8 Repositioning a mislocated rigid lens.

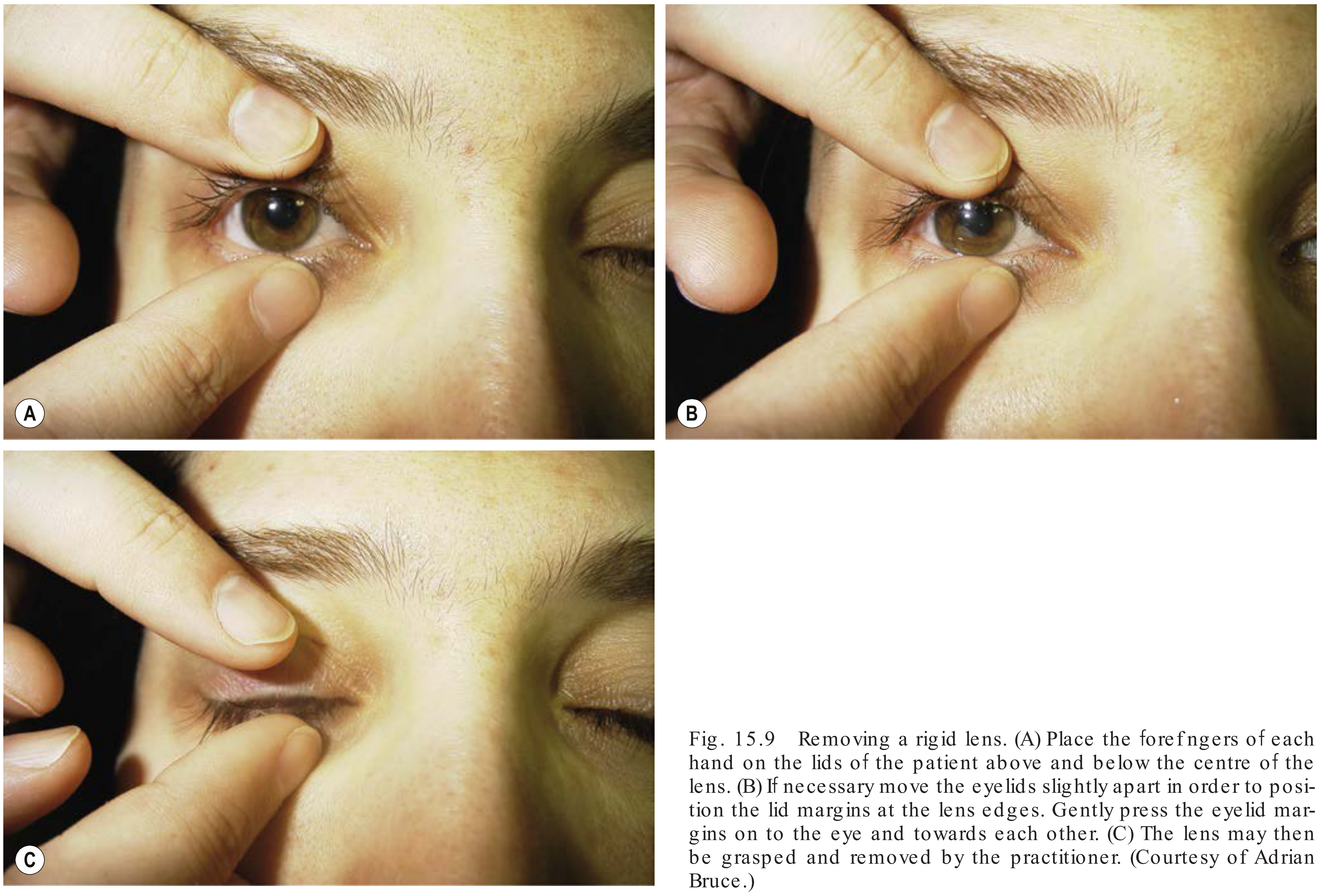


Fig. 15.9 Removing a rigid lens. (A) Place the forefingers of each hand on the lids of the patient above and below the centre of the lens. (B) If necessary move the eyelids slightly apart in order to position the lid margins at the lens edges. Gently press the eyelid margins on to the eye and towards each other. (C) The lens may then be grasped and removed by the practitioner. (Courtesy of Adrian Bruce.)

SETTLING TIME

With new wearers, the patient's initial reaction to rigid lenses is useful and can give an indication of how easily the patient will adapt to rigid lens wear. Clearly, those showing little or no lacrimation and who are able to move the eyes without apparent discomfort are the most promising candidates. In these cases, the lens fit can be assessed immediately. However, in most cases, it will be necessary to wait 5–10 minutes for any lacrimation to subside. This period can be used to discuss aspects of the process, such as costs and hygiene and to answer any questions.

In a few cases it may be some time before lacrimation subsides enough to allow examination. It is necessary, however, to consider other possible reasons for the discomfort. This might be due to a foreign body attached to the lens (the tears usually clear any loose foreign bodies) or, alternatively, the fit might be so poor as to be causing some mechanical trauma to the cornea or conjunctiva. Having ruled out other causes of discomfort, it might be necessary to give a longer settling period (e.g. 10–30 minutes). It is preferable that the patient does not leave the practice during this period.

Lens Fit Characteristics

OPTIMUM LENS FIT

A well-fitting rigid lens will centre in such a way that the pupil is fully covered by the optic zone while the eye is open. The lens should position within the limbal boundary. In the case of a lid attachment fit the lens edge will be positioned under the top lid, whereas with an interpalpebral fit the lens will be positioned between the lids. Also, lenses are occasionally designed with thicker edges incorporating a negative carrier in order to encourage lid attachment and lens centration. The requirements of a well-fitting rigid lens are summarized in Table 15.5.

SATISFACTORY LENS FIT

A lens with less than optimum fitting may drift downwards between blinks, but not so fast as to disrupt vision or irritate the bottom lid or lower limbus. It will move vertically with a blink, being first pushed as far as the lower limbus and then lifted by the lid almost to the upper limbus. In the case of with-the-rule astigmatism, the lens will pivot along the horizontal meridian or, if there is apical clearance, at the edge of the optic zone at the 3 and 9 o'clock corneal locations (Caroline et al., 1994).

Assessment of Lens Fit

There is a temptation to assess rigid lens fitting purely in terms of whether the lens is steep or flat; however, this approach fails to consider other aspects of rigid lens fit. In particular, when

TABLE 15.5 Requirements of a Well-fitting Rigid Lens

Requirement	Importance	Relevant Rigid Lens Parameters
Comfort	Patient satisfaction	Edge thickness Edge form Edge clearance Back surface junctions
Good centration	Corneal coverage Stable peripheral vision	Edge clearance BOZR Diameter
Movement on blink or version	Adequate post-lens lubrication Avoidance of lens adherence Supply of oxygen (low-Dk materials)	Diameter
Constant pupil coverage	Stable vision	BOZD
Adequate corneal alignment	Avoidance of excessive mechanical pressure	BOZR
Optimum edge clearance	Avoidance of mechanical disruption Comfort Avoidance of 3 and 9 o'clock staining	Peripheral curve radii Peripheral curve width

BOZR = back optical zone radius; BOZD = back optical zone diameter.

new to rigid lens fitting, it is helpful to work through the following checklist of fitting characteristics:

- diameter acceptability
- centration
- movement
- central fit
- edge clearance.

There is also a tendency to assess rigid lenses in only one position. However, during normal wear, rigid lenses move to all positions on the cornea and it is therefore necessary to assess the lens in a variety of positions, where necessary manipulating the lens through the lids to move it to different corneal locations. In particular, it is important to assess the peripheral fit of the lens when it decentres along the flattest meridian (e.g. at 3 and 9 o'clock in with-the-rule astigmatism).

Hand-held ultraviolet (UV)-illuminated magnifiers (Burton lamps) can be used for the assessment of rigid lens fit and have the advantage of allowing the patient to maintain normal head posture. This type of assessment is also relatively quick and allows the two eyes to be easily compared. On the other hand, the magnification is not good enough to evaluate some important aspects of fit, such as edge clearance. For this reason alone, slit-lamp evaluation is the method of choice for properly assessing rigid lens fit.

Some rigid lens materials contain a UV inhibitor that absorbs wavelengths corresponding to that emitted by Burton lamps, making fluorescein evaluation impossible. The blue filters on most slit lamps have a wider spectral range, which overcomes this problem.

WHITE LIGHT ASSESSMENT OF FIT

The position of the lens may change when fluorescein is added to the tear film. To avoid this confounding influence, the lens should first be assessed in white light prior to the instillation of fluorescein. It is necessary to ensure that the illumination setting of the slit-lamp biomicroscope is not so bright as to induce reflex tearing or an aversion reflex, which could cause the patient to adjust lid position.

Diameter

The lens should appear to be the appropriate size for the eye. With a relatively small lens, problems will tend to arise from decentration. The lens may fail to cover the cornea through sitting high or resting on the bottom lid. It may also be less comfortable because of greater interaction between the upper lid margin and the lens edge. Alternatively, the lens may irritate the bottom lid by dropping between blinks.

Lenses that are larger than the palpebral aperture can result in problems through interacting with the bottom lid as well as the top lid. In some cases, the lens will be pushed into a high-riding position by occasional interaction with the bottom lid, whereas in other cases the lens may rest on the bottom lid.

Centration

The lens diameter may appear to be appropriate for the corneal diameter and palpebral aperture but nevertheless show some decentration. The position of the lens between blinks is important. Some decentration may be acceptable if the optic zone maintains pupil coverage, but this may also indicate poor central or peripheral fit. Flat-fitting lenses, for example, can show decentration in any direction, depending on factors such as lid position or tightness.

Movement

All rigid lenses, however steep, show some movement. The task, therefore, is to assess the extent, speed and direction of movement. This should be observed in normal primary gaze. Sluggish, limited post-blink movement may indicate a relatively steep-fitting lens. Fast movement sometimes indicates a flat-fitting lens but may also be due to strong interaction with the top lid, perhaps due to excessive edge clearance.

In addition, it is sometimes useful to retract the lids and observe the lens moving under gravity alone. Hold the lids apart and manoeuvre the lens upwards. On releasing the lens, it should drop slowly. If the lens shows less movement without the influence of the lids, this would suggest excessive lid interaction. A true flat-fitting lens often shows downward movement in an arcuate direction.

Peripheral Fit

Instances of markedly excessive edge clearance can be observed with white light. The peripheral tear meniscus may be absent, particularly in the steeper meridian. In severe cases, this results in bubbles forming behind the lens, which in turn can lead to dimple staining. Patients also tend to find such lenses uncomfortable owing to excessive interaction with the sensitive lid margins.

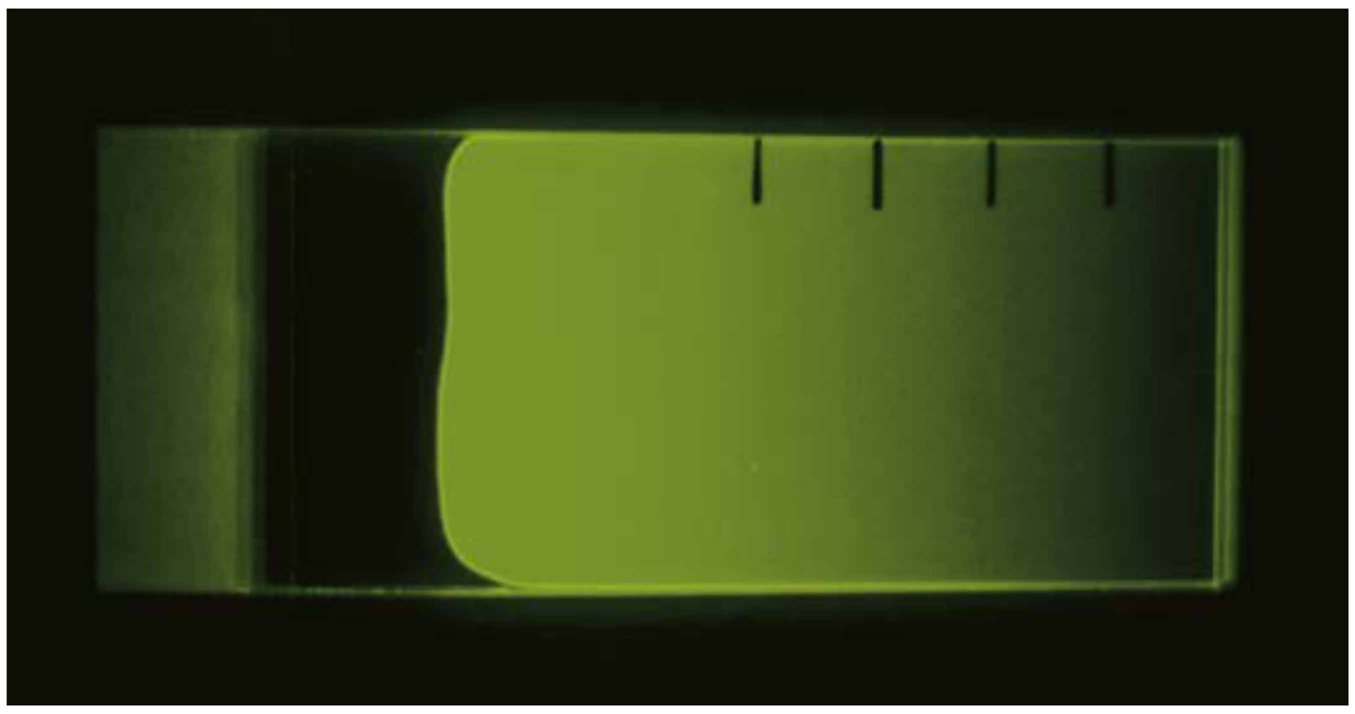


Fig. 15.10 Fluorescein wedge. Two converging glass plates are filled with fluorescein; the plates are touching at the right side of the wedge.

FLUORESCEIN ASSESSMENT OF FIT

Interpretation of Fluorescence

Fluorescein sodium is soluble in water. It absorbs most light in the blue part of the spectrum but most of its emitted light is in the yellow part of the spectrum and some in the green. The intensity of light emitted is governed by the concentration and pH of the solution, and, critically in rigid lens fitting, the thickness of the fluorescein sample. The effect of concentration and thickness of fluorescein can be analysed using wedges of fluorescein (Fig. 15.10). At the thinner end of the wedge, fluorescein is not visible until a critical thickness of about 15 µm is reached. The intensity can be seen to increase towards the thicker end of the wedge until another critical thickness of about 60 µm is reached, beyond which the fluorescein is seen as a uniform bright-yellow colour (Young, 1988).

In rigid lens fitting, the fluorescein pattern is a simple two-dimensional representation of a complex three-dimensional shape. This provides useful information about the relationship of the lens with the shape of the eye. Areas of tear pooling appear bright yellow. Where the tear layer is absent or extremely thin, there is no visible fluorescence and the area appears dark blue or black. Between these extremes, varying thicknesses of post-lens tear film are seen in varying intensities of yellow/green. Fluorescein therefore provides a contour map of the thickness of the tear film.

Fluorescein Instillation

As noted earlier, excessive fluorescein will disrupt the lens fit and it is therefore best to instil a minimal amount, preferably from a fluorescein strip. Placing a drop of fluorescein on the superior sclera will maximize the length of time the dye remains in the eye. In particularly sensitive patients, the process can be simplified by touching the fluorescein strip against the front of the lens.

A thick fluorescein-stained pre-lens tear film may confound interpretation of the true post-lens fluorescein pattern (the object of interest), so it may be necessary to wait until this has dissipated before assessing the pattern.

Three primary annular regions of the fluorescein fit should be evaluated systematically: the central fit, the peripheral fit and the edge clearance. In the case of a tricurve lens, these three annular zones essentially correspond to the three back surface zones of the lens. It is important to note areas showing no fluorescence as well as those that do.

As with the assessment of corneal staining, it is helpful to use a yellow filter to enhance the visualization of the fluorescein.

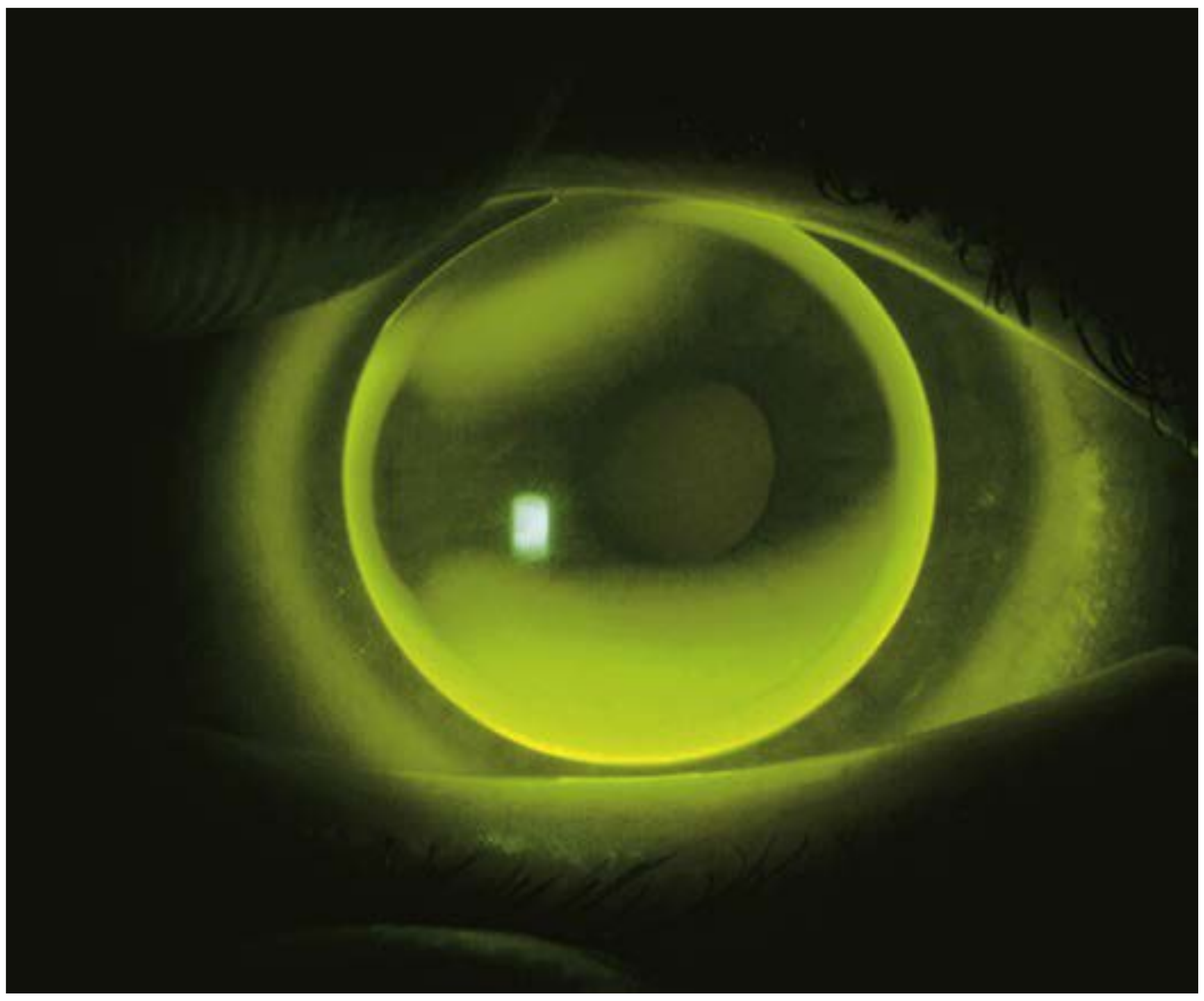


Fig. 15.11 Assessing central fluorescein fit having centred the lens and retracted the top lid.

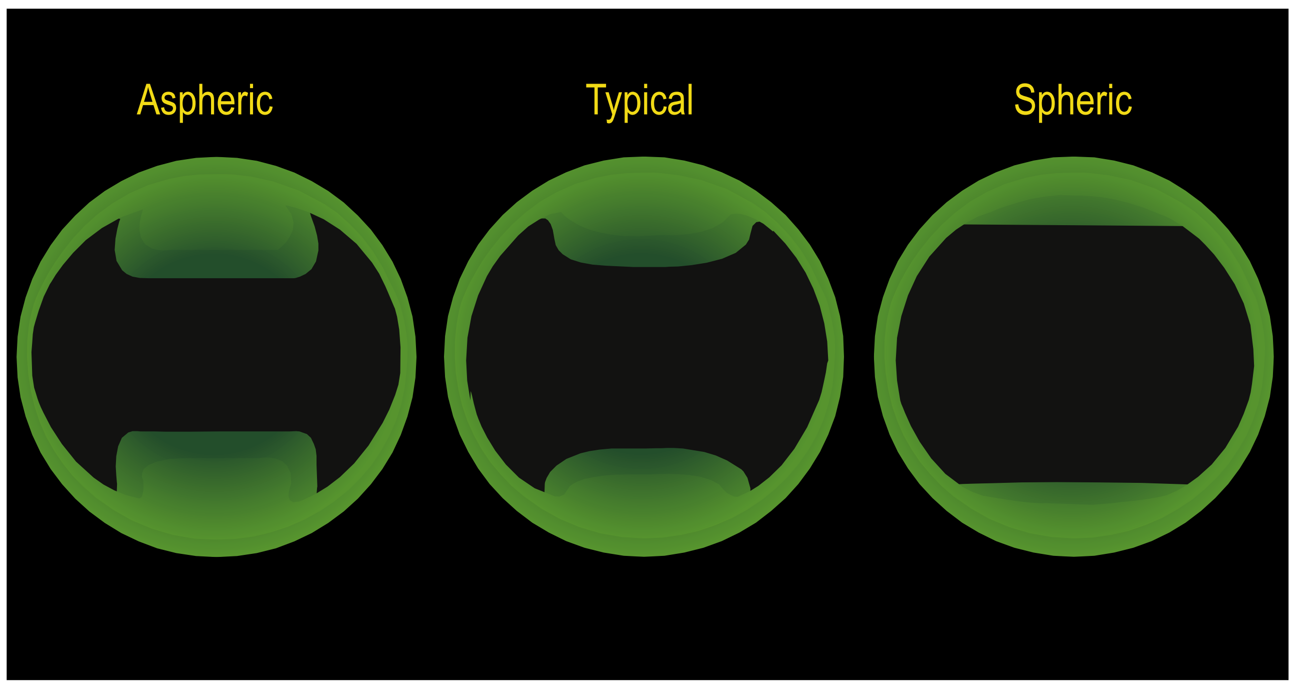


Fig. 15.12 Typical fluorescein pattern with well-fitting lens on astigmatic (1.00 D) corneas of similar K-readings but varying corneal asphericity (corneal shape factors = 0.60, 0.85 and 1.10).

Central Fit

If the lens is half covered by the top lid, or the lens is decentred, it may not be possible to observe the central fit without retracting the lid and repositioning the lens. This is achieved by gently holding the top and bottom lids with the index finger and thumb, respectively (Fig. 15.11). The lids can be used to manoeuvre the lens into a central position and also to pump extra fluorescein beneath the lens.

The fluorescein pattern for well-fitting lenses will vary according to corneal asphericity and astigmatism. As one would expect, spherical corneas show the simplest fluorescein patterns. The optimum fit is one that shows central alignment or just a trace of fluorescein indicating minimal central clearance.

With astigmatic corneas, in the steeper meridian the central fluorescein pattern will show increasing thickness towards the edge. The most recognizable fluorescein pattern is the 'dumbbell' pattern seen with spherical lenses on astigmatic corneas (see Fig. 15.11); however, the pattern varies according to the:

- asphericity of the cornea (Fig. 15.12)
- amount of corneal astigmatism (Fig. 15.13)
- lens design
- fitting relationship, i.e. whether the lens is relatively steep or flat.

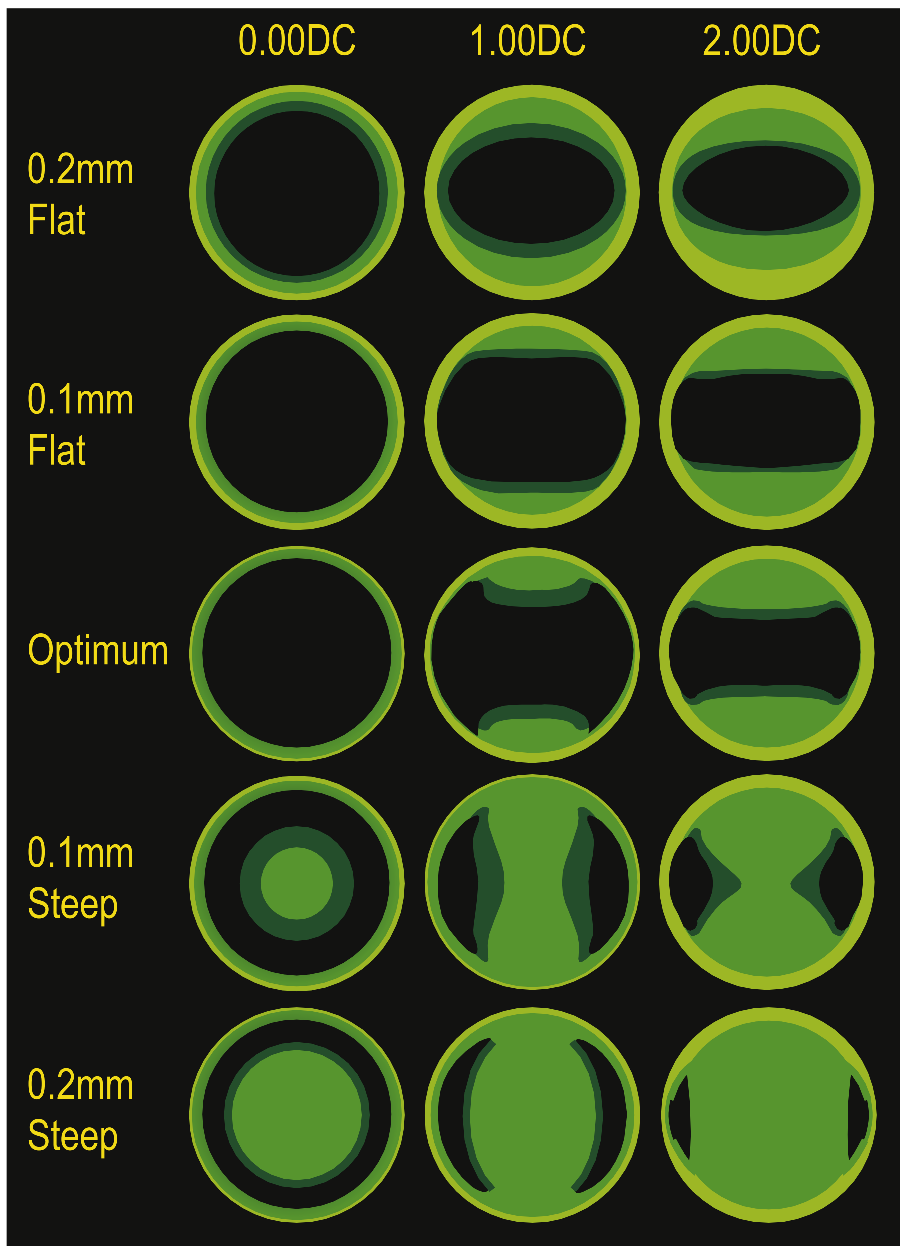


Fig. 15.13 Fluorescein patterns of rigid lens of varying back optic zone radius on with-the-rule corneas of varying astigmatism.

With steep-fitting lenses, fluorescein assessment will show a central pool of fluorescein. This pool will appear brighter the steeper the fit. In extreme cases, an air bubble may be present.

With flat-fitting lenses, central touch will be visible as an area of dark blue or black. The flatter the fit, the smaller the area of touch. Fluorescein will be present in the mid-periphery and may be continuous with the peripheral band of fluorescein.

Mid-peripheral Fit

Spherical lenses, particularly on astigmatic eyes, make contact with the cornea at the edge of the optic zone. If the lens is poorly blended or makes contact at a sharp angle, it may be uncomfortable and cause epithelial disruption. If a narrow line of contact between optic zones can be seen upon lens inspection, it is likely that there is a sharp junction from poor blending. A band of contact corresponding to the first peripheral zone may indicate relatively steep peripheral curves and the need for peripheral lens flattening.

In the case of a flat-fitting lens, the mid-peripheral band of fluorescein may merge with that of the central zone, even in the flattest meridian.

Edge Fit

The width and the brightness of the peripheral band of fluorescein give an indication of the extent of edge clearance. Where the edge clearance is small, the tear film thickness may be less than the critical thickness above which the fluorescein appears with a saturated yellow colour. This is generally less than the desired clearance of 80 µm or more. A less-than-bright yellow peripheral ring therefore indicates suboptimal edge clearance. This will be confirmed by an apparent break in the peripheral band of fluorescein when the lens decentres towards the limbus.

In the case of excessive edge clearance, bubbles may be seen forming under the lens periphery. The peripheral band may also be wider than expected and show the saturated yellow appearance over much of the peripheral band.

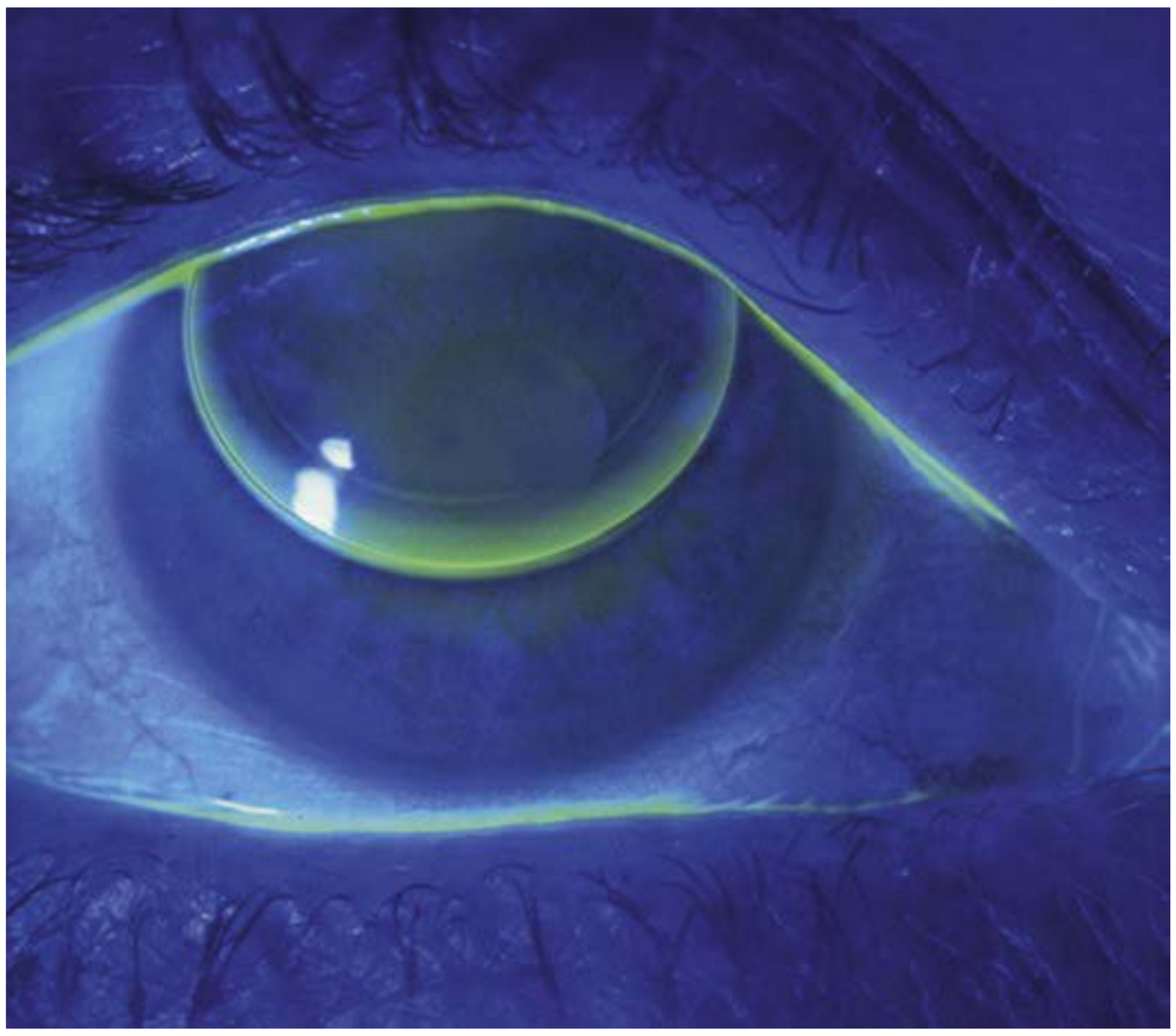


Fig. 15.14 High-riding rigid lens.

OVERREFRACTION

Measuring the overrefraction during a rigid lens trial fitting not only helps to determine the final lens power but also gives an indication of whether the optimum fit has been obtained. An unexpected overrefraction suggests that either the lens is wrongly labelled or the fit is not perfect. The steeper the lens fit, the more minus power will be required in order to compensate for a relatively plus-powered tear lens. Variable vision may indicate a decentred or flat-fitting and relatively mobile lens fit.

As a rule of thumb, a change in BOZR of 0.05 mm requires a change in BVP of 0.25 D in order to compensate for the change in tear lens. For instance, if a lens requires steepening by 0.10 mm and the overrefraction is plano, then the minus power of the lens will need to be increased by −0.50 D.

Rigid Lens Fitting Problems

DECENTRATION

Poor centration is more common with higher levels of astigmatism. In the case of with-the-rule astigmatism the decentration tends to be upwards (Fig. 15.14), whereas in the case of against-the-rule astigmatism it tends to be sideways.

Decentration can be investigated as follows:

1. Check whether the central fit is relatively flat. A change in BOZR of 0.05 or 0.10 mm is unlikely to have much effect on centration; however, larger changes than this may make a critical difference.
2. Check that the edge clearance and edge thickness are not excessive and resulting in undue lid influence. In particular, this is often the case with a high-riding lens.
3. Assuming no fundamental errors in fit, the next approach is to consider an increase in overall diameter and optic zone diameter. The lens may still show some decentration, but this is acceptable so long as there is pupil coverage by the optic zone.
4. If the decentration is deemed to be due to corneal astigmatism, consider refitting with a back-surface toric design (see Chapter 16).

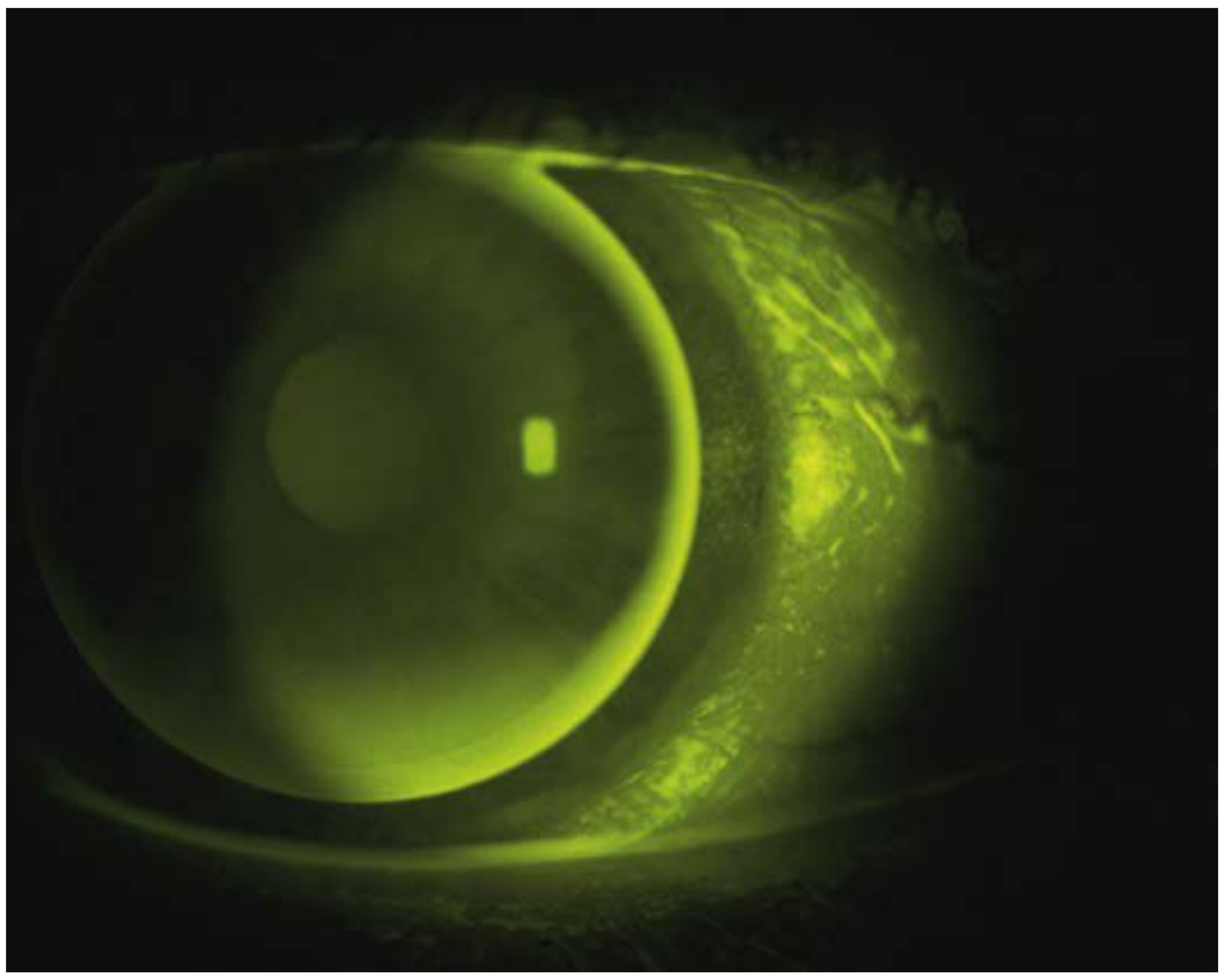


Fig. 15.15 Mild 3 and 9 o'clock staining (shown here in the 3 o'clock location).

PERIPHERAL CORNEAL DESICCATION

The appearance of 3 and 9 o'clock corneal staining can arise due to either mechanical trauma or, more commonly, desiccation. The extent of staining does not correlate with patient symptoms (van der Worp et al., 2009). Some minimal 3 and 9 o'clock desiccation staining is considered acceptable; however, coalescent or widespread staining can lead to vascularization, scarring and corneal thinning (dellen) – conditions that often require remedial attention. The characteristic appearance of 3 and 9 o'clock staining is a triangular shape delineating those areas not wetted by the action of the upper lid. The apex of the triangle corresponds to the location of the widest part of the lens (Fig. 15.15). Research suggests that the incidence of 3 and 9 o'clock staining is lower with larger lenses (>9.5 mm) incorporating a moderately wide tear reservoir (Schnider et al., 1997).

A number of factors can contribute to 3 and 9 o'clock desiccation staining including:

- infrequent blinking
- poor tear quality
- inferior lens decentration
- excessive lid clearance due to lens edge clearance or edge thickness (Schnider et al., 1996).

A diverse range of possible treatment options has been proposed to overcome this type of staining (van der Worp et al., 2003). The following are the most useful options:

- Encourage blink awareness if the patient demonstrates partial or infrequent blinking.
- Modify the lens to reduce edge thickness.
- Blend the back-surface junctions, if appropriate, to reduce edge clearance.
- Refinish the lens edge to reduce the diameter and therefore reduce edge clearance.
- Redesign the lens to reduce edge clearance.
- Increase the diameter, incorporating a wide peripheral band.
- Refit with soft lenses – this can be surprisingly successful even when tear film quality is a contributing factor.

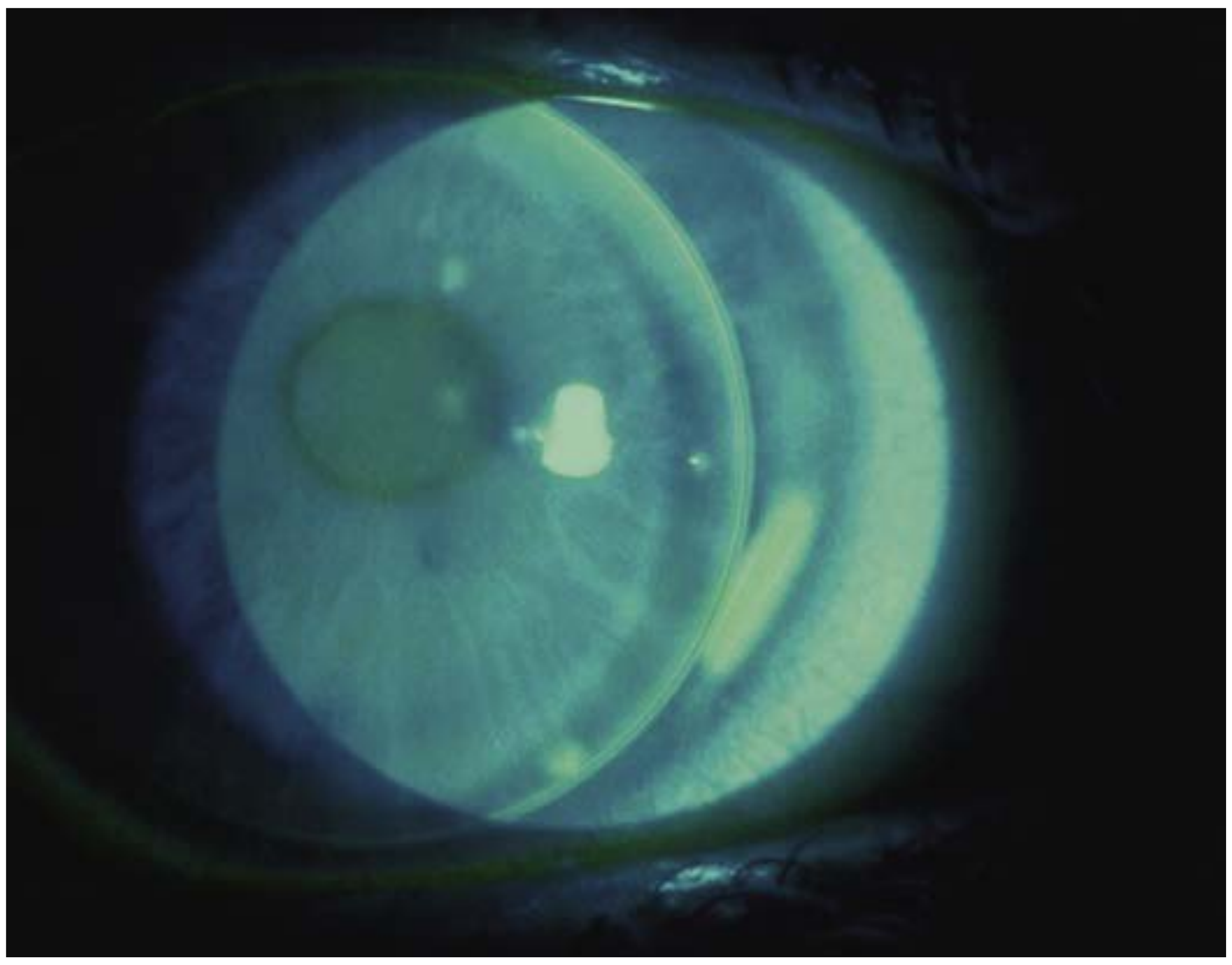


Fig. 15.16 Poor edge clearance with a rigid lens with resultant confluent staining.

PERIPHERAL CORNEAL MECHANICAL TRAUMA

Desiccation 3 and 9 o'clock staining can be mistaken for mechanically induced staining resulting from poor edge clearance. A lens may show adequate edge clearance when centred but exert mechanical pressure when decentred towards the limbus. On examination of the fluorescein fit, the staining coincides with an arcuate area of contact (Fig. 15.16). This problem may be remedied as follows:

- Modify the existing lens to increase edge clearance, assuming that the lens periphery is thick enough.
- Redesign the lens with increased edge clearance.

Substantial changes in peripheral curve radii are required to effect a significant change in edge clearance (Young, 1998). For instance, with a 9.5 mm diameter tricurve design, flattening both peripheral curves by 0.25 mm is required to achieve a minimal significant change in edge clearance of about 10 µm.

DISCOMFORT

The most common reason for discontinuing rigid lens wear is discomfort. The description of symptoms offered by (or elicited from) the patient can be helpful in determining the cause of the problem, such as whether the discomfort arises from the cornea, palpebral conjunctiva or lid margin; whether it arises from symptoms of dryness, edge sensation or mechanical pressure on the cornea; or whether it is connected with any particular activity or environment.

Possible modifications to rigid lens designs that might improve comfort include:

- reblending the back-surface optic zone transitions
- rerounding and/or thinning the edges
- reducing edge clearance by reducing the TD
- increasing the TD
- refitting with an aspheric design.

The first three of the strategies described above can be undertaken by modifying an existing lens as opposed to making a new lens. Such modifications can be undertaken in the practice if suitable equipment is available; however, lens modification requires some skill (Phillips, 2007) and most practitioners prefer to instruct a lens laboratory to undertake such tasks.

If the problem can be alleviated by modification, redesign or some change in lens wearing habits, then clearly these steps should be followed. However, after taking such actions and allowing for a reasonable period of adaptation to rigid lens wear, some patients report that the discomfort remains unacceptable. Such patients may never adapt to comfortable rigid lens wear and other options should be considered, the obvious one being a change to soft lenses. Alternatively a hybrid lens design may be preferable in the case of an irregular cornea.

POOR OR UNSTABLE VISION

The accepted tolerances in rigid lens manufacture are relatively wide. Because errors in BOZR and BOZD as well as BVP affect the refractive correction, a rigid lens can be within tolerance but still under- or overcorrect by nearly 1.00 D. In this case, an overrefraction will bring the visual acuity back to normal. If, however, the vision quality is still poor, the following factors should be considered:

- poor surface wetting – if new, the lens may not have been sufficiently hydrated
- optical distortion – occasionally waves in the polymer or on the surface of the lens can disturb vision; these can be observed by cleaning the lens and looking through it with the naked eye
- surface scratches – can usually be polished out of the lens
- surface deposits – normally removable with a surface cleaner, particularly an abrasive surface cleaner.

Variable vision can arise either through inadequate pupil coverage (small BOZD or decentration) or poor surface quality (scratches, deposits or poor wetting).

LENS LOSS

Rigid lens wearers who do not have spare lenses are at a disadvantage compared with most soft lens wearers, for whom the loss of an occasional disposable lens is not a problem. The repeated loss of a rigid lens may relate to the lens design. Tight lids combined with generous edge clearance can result in a lens being flipped out of the eye. Apart from optimizing the edge clearance, increasing the lens diameter can also help to make lenses more secure. In the case of significant corneal astigmatism, it may also be necessary to consider a back-surface toric design.

Practitioners should be cognizant of the fact that reports of lost lenses may be due to the lens becoming mislocated and sometimes embedded beneath the upper eyelid, unknown to the patient. Numerous reports have appeared in the literature describing this phenomenon, the most astonishing being that of Kelly (1994), who described the case of a female patient who had reported losing numerous rigid lenses over a 3-month period. A mucus-coated pellet was eventually removed from beneath her upper eyelid: this comprised eight PMMA lenses and one rigid gas-permeable lens.

Conclusion

Although most lenses prescribed today are soft lenses, there is still a role for rigid lenses. Advances in lens material technology have enabled rigid lenses that interfere minimally with ocular physiology. In some cases of poor corneal optics, rigid lenses are the only optical solution short of keratoplasty. However, as has been demonstrated above, rigid lenses are far less forgiving than soft lenses in terms of fitting characteristics and comfort. Successful rigid lens fitting therefore demands patience, careful patient management and good skill levels on the part of the practitioner, coupled with perseverance and understanding on the part of the patient.

Access the complete references list online at http://www.expertconsult.com.

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16

Rigid Toric Lens Design and Fitting

RICHARD G LINDSAY

Introduction

The use of rigid toric lenses (in preference to rigid spherical lenses) is indicated under the following circumstances:

1. to improve the vision in cases where a lens employing spherical front and back optic zone radii is unable to provide adequate refractive correction
2. to improve the physical fit in cases where a lens with a spherical back optic zone radius (BOZR) and spherical back peripheral zone radii fails to provide an adequate physical fit.

These two main uses of toroidal surfaces on contact lenses are not always distinct, such that occasionally a toric lens will be used for both physical and optical reasons. For example, when fitting an eye with both a high degree of residual astigmatism and a large amount of corneal toricity, a toric lens is required optically (to correct the residual astigmatism) as well as physically (to optimize the fit of the lens) (Lindsay, 1996).

Forms of Toric Lens

There are many varieties of rigid toric lens available to the practitioner. Most commonly, a lens will have both a toroidal back optic zone and peripheral zone. These lenses are generally used in attempting to obtain a good physical fit on a cornea that is too toroidal to allow a good fit with a lens having a spherical BOZR and spherical peripheral radii. Lenses with toroidal back optic and peripheral zones can be produced with or without a toroidal front optic surface. A lens that has a toroidal back optic zone and a toroidal front surface is said to have a bitoric construction. If the principal meridians are not parallel, then the lens is designated as having an oblique bitoric construction.

Occasionally, a rigid toric lens may be prescribed, consisting of a spherical back optic zone and a toroidal peripheral zone. This type of lens can also be produced with or without a toroidal front surface, the latter usually being the preferred option. Lenses with spherical back optic zones and toroidal peripheral zones are used as a means of attempting to improve the physical fit of a lens on an astigmatic cornea without the optical complications inherent in the use of lenses with toroidal back optic zones.

Very rarely, a rigid toric lens is produced with a toroidal back optic zone and a spherical peripheral zone, with the intention of improving the circulation of tears beneath the lens. However, when this is done, it is possible that the lens may become less stable with regard to resisting rotation. One limitation of employing a spherical periphery is that the peripheral radius must be greater than, or equal to, the flatter radius of the toroidal back central optic zone. Once again, this form of lens can be made with or without a toroidal front surface.

The only other rigid toric lens form consists of a spherical back optic zone and spherical peripheral zone combined with a toroidal front optic surface. This type of lens is required in the situation where there is significant residual (non-corneal) astigmatism but minimal corneal astigmatism. In this case, the residual astigmatism needs to be corrected by means of a toroidal front surface, with a spherical optic zone indicated for the back surface owing to the negligible corneal astigmatism.

Criteria for Use

Since rigid lenses with both spherical BOZR and peripheral radii are often used successfully on corneas with medium to high degrees of astigmatism, it is important to decide what degree of corneal astigmatism should indicate the use of toroidal back optic zones. In general, these lenses should be used only when a lens with a spherical BOZR cannot be made to fit successfully. It is rare to find that toroidal back optic zones are necessary unless the corneal astigmatism exceeds 2.50 D (i.e. the difference in the corneal radii, as measured with a keratometer, exceeds approximately 0.5 mm).

In cases of uncertainty (e.g. where the corneal astigmatism is between 2.00 and 3.00 D), a toroidal back optic zone would be used in preference to a spherical back-surface curve in the following situations:

- A spherical lens exhibits poor centration or excessive movement.
- Excessive lens flexure is noted with a spherical lens.
- Fluorescein patterns with a spherical lens reveal excessive bearing along the flatter corneal meridian, regardless of the BOZR that is fitted.
- Significant 3 and 9 o'clock staining occurs with a spherical lens.
- There is marked corneal distortion and spectacle blur upon removal of the spherical lens from the eye. This occurs as a result of poor alignment between the spherical lens and the toric cornea, with the spherical lens subsequently having a moulding effect on the toric cornea.
- There is significant residual astigmatism. In this case, a spherical back surface may provide an adequate fit; however, a toric back surface is utilized to stabilize the lens and prevent rotation, owing to the presence of the correction for the residual astigmatism on the front surface of the lens.

A great deal depends on factors other than corneal astigmatism. Lid positions and tension are important. In a case of high with-the-rule corneal astigmatism – and a low, loose lower lid – a toroidal back optic zone may be needed to obtain a good physical fit and centration. But a similar eye with a firm, high lower lid may well be successfully fitted using a lens with spherical back-surface curves.

The majority of cases of corneal astigmatism are found with the steeper corneal curve in the vertical meridian (with-the-rule). If an attempt is made to fit such an eye with a spherical BOZR, the lens often exhibits harsh bearing along the flatter (horizontal) meridian of the cornea and poor centration, causing physical discomfort and / or poor vision. Such an example is illustrated in Fig. 16.1. If the same eye is fitted using a lens with toroidal back optic and peripheral curves, then the physical fit and centration are usually much improved (Fig. 16.2).

The presence of against-the-rule corneal astigmatism usually necessitates the use of a toroidal back optic zone earlier than would be required with an equivalent amount of with-the-rule corneal astigmatism. This is due to the tendency for rigid spherical lenses to decentre laterally on corneas with even moderate amounts (1.50–2.00 D) of against-the-rule astigmatism.

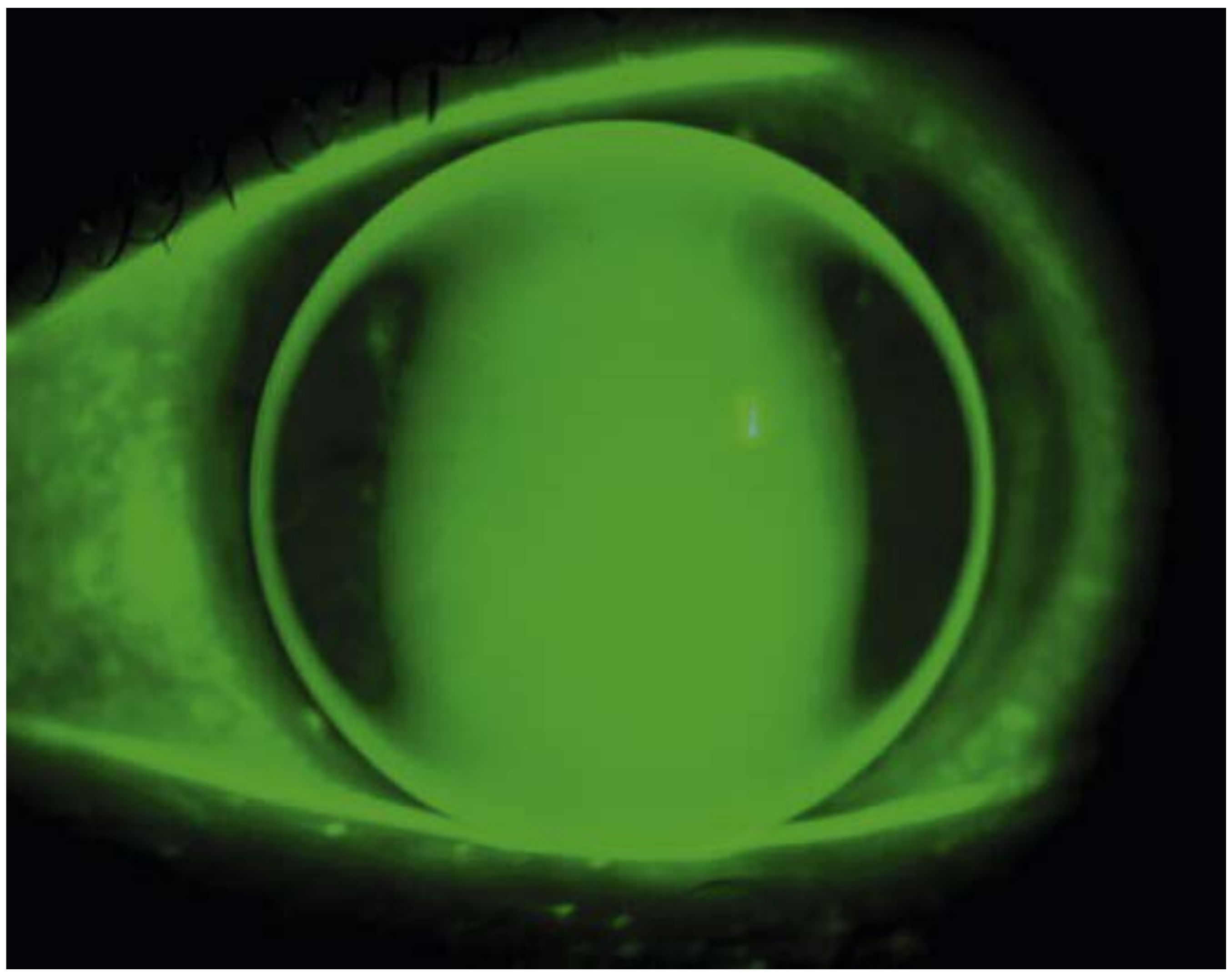

Fig. 16.1 Left eye with high corneal astigmatism. Keratometer reading 8.19 mm along 176, 7.47 mm along 86. Fitting with spherical (7.70 mm) back optic zone radius reveals harsh bearing along the horizontal (flatter) meridian and poor centration.

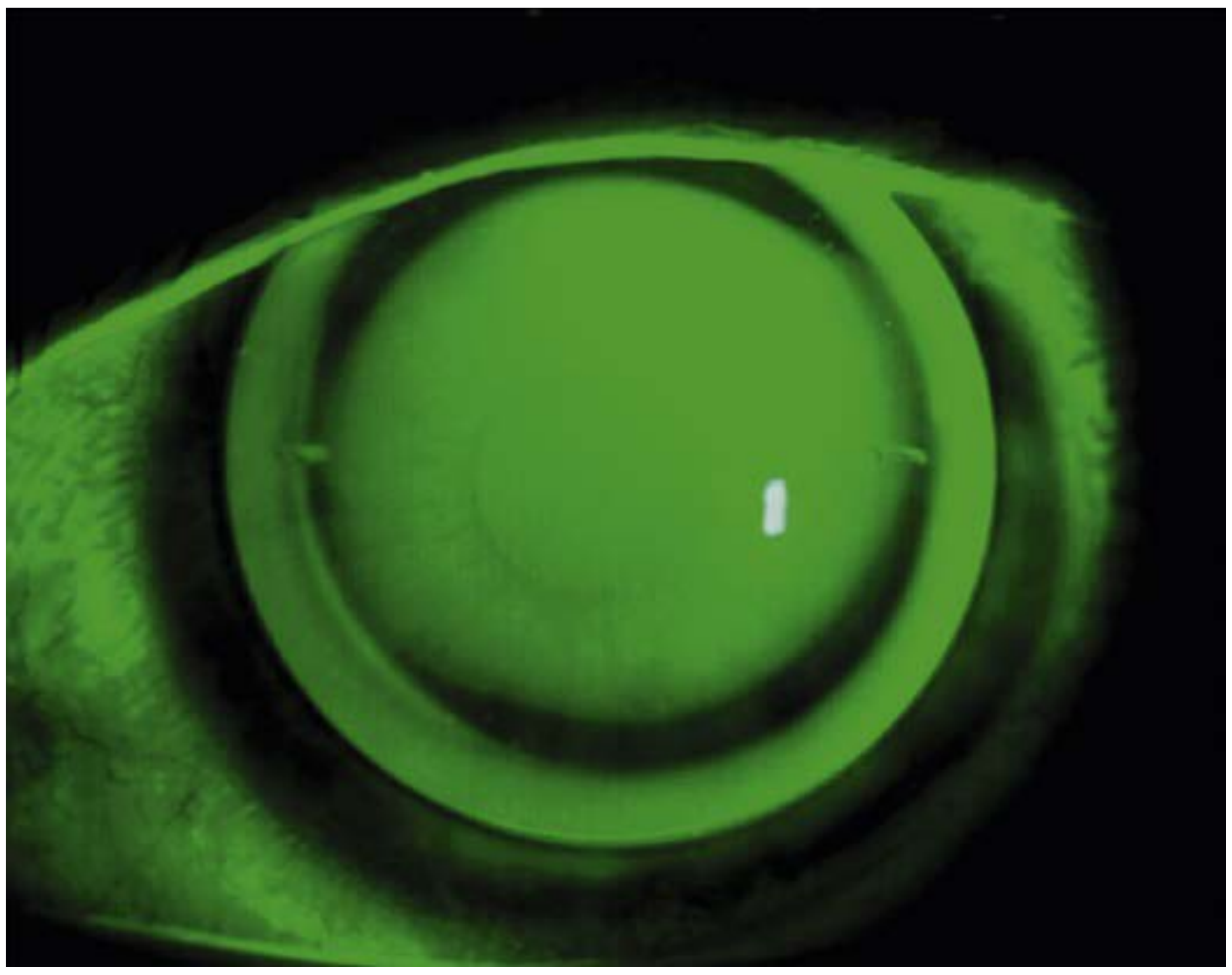

Fig. 16.2 Same left eye as in Fig. 16.1 wearing an alignment fitted rigid lens using a toroidal curve of back optic zone radius 8.15 × 7.50 mm.

Design Considerations

Although rigid lenses may be successfully fitted with either apical clearance or apical contact, it is generally more satisfactory to fit lenses with toroidal back optic zones in or near alignment. The physical fit, as denoted by the fluorescein pattern, will be similar to that seen with a well-fitted spherical lens in alignment to a cornea devoid of clinically significant astigmatism.

A toric lens aligning too closely to the cornea can lead to poor tear interchange. Consequently, it is advisable to use a toroidal back optic zone with the steeper radius fitted slightly flatter (longer radius) than the corresponding corneal radius so as to assist the interchange of tears. The flatter radius will generally be fitted 'on K' or else slightly steeper than its corresponding corneal radius.

Consider the type of physical fitting that might be derived from keratometer readings:

Keratometry reading: 7.90 mm (42.72 D) along 180
7.35 mm (45.91 D) along 90

$$\text{Prescribed lens : C3 toric}\Big/\frac{7.85}{7.40}:7.50\Big/\frac{8.45}{8.00}:8.50\Big/\frac{9.25}{8.80}:9.50$$

The back optic zone radii should always be chosen such that there is at least a 0.3 mm meridional difference in radii (or 1.50 D difference if the BOZR are specified in dioptres). Otherwise, the toroidal BOZR may not position properly on the toroidal cornea, leading to lens rotation and possible visual disturbance, depending on the type of toric lens design. (Note that BOZR indicates back optic zone radius for a spherical surface and back optic zone radii for a toroidal surface.)

The peripheral radii are usually chosen to reflect the type of peripheral fit preferred by the practitioner concerned. Each meridian is considered separately, and the peripheral fittings in the two principal meridians are selected to provide the same difference between back optic and peripheral radii most commonly used by the practitioner in fitting spherical corneas. In addition, the peripheral curves will usually have the same degree of toricity as the BOZR. For example, if a practitioner usually specifies the secondary curve 0.9 mm flatter than the BOZR for a spherical lens, then for a lens with toroidal BOZR of 7.90 / 7.40 the secondary curve ordered would be 8.80 / 8.30.

For lenses with a spherical back optic zone and a toroidal peripheral zone, the peripheral curve region should be as large as possible to increase the likelihood of alignment with the toric cornea. These lenses are usually fitted fairly small to minimize meridional sag differences and slightly steeper centrally than the flatter corneal meridian to achieve a compromise fit. The meridional difference in the peripheral curves should be at least 0.6 mm to help minimize lens rotation (Ruston, 1999).

A typical case might be as follows:

Keratometry reading: 7.90 mm (42.72 D) along 180
7.30 mm (46.23 D) along 90

BOZR chosen: 7.70 mm
BOZD chosen: 6.50 mm
TD chosen: 9.50 mm
Prescribed lens:

$$\text{C4/7.70 : 6.50}\Big/\frac{8.50}{7.90}:7.50\Big/\frac{9.20}{8.60}:8.50\Big/\frac{10.00}{9.40}:9.50$$

Although this type of lens can be very useful in certain cases where a fully spherical lens is not adequate, the toroidal peripheral zones are, at best, only an attempt at compromise. They usually rotate more than lenses with all toroidal back-surface curves, and the steeper peripheral radii occasionally end up in close proximity to the flatter corneal meridian, thus causing slight corneal abuse.

Optical Considerations

The calculations involved in determining the necessary radii and power of these lenses are quite straightforward and the complexity of this topic is often exaggerated. It is important, however, that the fundamentals of the optics of contact lenses are understood if some of the complications of toroidal optic surfaces on corneal lenses are to be appreciated.

To help understand and perform some of the calculations needed in toric lens work, the reader is referred to Chapter 13 and also to Douthwaite (1995).

REFRACTION

Calculating the back vertex powers (BVPs) for a rigid lens with toroidal back optic zone is undoubtedly a more complex task than determining the BVP for a spherical lens, and yet the two processes involve the same basic principles. For spherical lenses, the power of the contact lens in air plus the power of the tear lens in air should add up to the ocular refraction. With toric lenses, the same rule applies, but here the two separate meridians must be considered.

Example 1: Calculating the back vertex power for a rigid lens with a toroidal back optic zone
Spectacle refraction (vertex distance ignored):

$+2.50/-3.00 \times 180$

(Note that the effect of the vertex distance must be taken into account if this distance is great or if the refractive power in either meridian exceeds 4.00 D.)

Keratometry reading: 8.04 mm (42.00 D) along 180
7.50 mm (45.00 D) along 90

A rigid spherical trial lens with BOZR 7.95 mm and BVP +1.00 D is placed on the cornea. Refraction with this lens in situ gives +1.00 DS (no residual astigmatism) and 6/6 acuity. Note that the overrefraction is usually best performed over a spherical trial contact lens aligned along the flattest meridian of the cornea and only one overrefraction is required to calculate both BVPs.

Based on the keratometry readings, BOZR of 8.00 mm and 7.55 mm are chosen to fit the horizontal and vertical meridians, respectively.

The power determination is now performed in the same way as with a rigid spherical lens, except that two meridians need to be considered instead of one. The BVP that needs to be ordered (BVP_{CL}) is calculated by taking into account the BVP of the trial lens (BVP_{trial}) and the overrefraction (OR) and then using the formula:

$$BVP_{CL} = BVP_{trial} + OR.$$

For a spherical lens, if the BOZR of the trial lens is different from the BOZR to be ordered, then, when determining the BVP_{CL}, it is necessary to take into account the change in tear lens power that will occur as a result of changing the BOZR.

Based on a tear lens refractive index of 1.336, this change in tear lens power is given by the formula:

$$\left(\frac{336}{BOZR_{final}} - \frac{336}{BOZR_{trial}}\right)$$

where $BOZR_{final}$ is the BOZR that has been chosen for the lens to be ordered and $BOZR_{trial}$ is the BOZR of the trial lens.

It can be approximated that, for every 0.05 mm decrease in BOZR, −0.25 D must be added to the BVP of the contact lens. Likewise, +0.25 D must be added to the BVP of the contact lens for every 0.05 mm increase in BOZR. This approximation holds only for relatively small differences in BOZR and, if in doubt, it is safer to use the above formula.

Given that the BOZR is being changed from that used for the fitting, the BVP that needs to be ordered (BVP_{CL}) is given by:

$$BVP_{CL} = BVP_{trial} + OR - \left(\frac{336}{BOZR_{final}} - \frac{336}{BOZR_{trial}}\right)$$

When calculating the BVPs for a rigid toric lens based on fitting with a spherical trial lens, there will be a change to the trial lens BOZR in at least one meridian. In this example, the back optic zone radii to be ordered are both different from the trial lens BOZR and so it will be necessary to allow for the change in tear lens power in both meridians.

$$\text{Along 180, } BVP_{CL} = +1.00 + 1.00 - \left(\frac{336}{8.00} - \frac{336}{7.95}\right) = +2.25\ \text{D}$$

$$\text{Along 90, } BVP_{CL} = +1.00 + 1.00 - \left(\frac{336}{7.55} - \frac{336}{7.95}\right) = -0.25\ \text{D}$$

(When calculating BVP, values are rounded off to the nearest 0.25 D.)
Final prescription (Rx) of lens:
BOZR 8.00 mm along 180 +2.25 D
BOZR 7.55 mm along 90 −0.25 D

Alternatively, the BVPs of the contact lens can be calculated empirically, by first using the required BOZR and the keratometry reading of the patient to calculate the tear lens power (BVP_{tears}) and then using the formula:

$$BVP_{CL} = \text{ocular refraction} - BVP_{tears}$$

to calculate the BVPs along both meridians.

The power of the tear lens is obtained from the following formula:

$$BVP_{tears} = \left(\frac{336}{BOZR} - \frac{336}{K}\right)$$

where K is the corneal front-surface radius of curvature (in millimetres) along that respective meridian.

Once again, it can be approximated (for very small differences) that there is 0.25 D of tear lens power for every 0.05 mm difference between the BOZR and the corneal front-surface radius of curvature.

Along 180,

$$BVP_{tears} = +2.50 - \left(\frac{336}{8.00} - \frac{336}{8.04}\right) \approx +0.25\ \text{D}$$

$$BVP_{CL} = +2.50 - 0.25 = +2.25\ \text{D}$$

Along 90,

$$\mathrm{BVP}_{\mathrm{tears}} = +\,2.50 - \left(\frac{336}{7.55} - \frac{336}{7.50}\right) \approx -\,0.25\ \mathrm{D}$$

$$\mathrm{BVP}_{\mathrm{CL}} = -\,0.50 - (-\,0.25) = -\,0.25\ \mathrm{D}$$

Although the empirical method is probably simpler, clinical experience would suggest that more accurate results are usually obtained when the BVP is calculated based on a refraction over a trial lens.

RESIDUAL ASTIGMATISM

The term 'residual astigmatism' is often used loosely and is frequently confused with induced astigmatism or corneal astigmatism. Residual astigmatism has been defined in various ways (Goldberg, 1964), including the simplistic definition of residual astigmatism as the component of the spectacle (ocular) astigmatism that is not due to the cornea. In the context of rigid lens fitting, a better definition would be: residual astigmatism is the astigmatic component of a lens required to correct fully an eye wearing a spherical powered rigid contact lens with a spherical BOZR.

Example 2: Calculating the back vertex power for a rigid lens with a toroidal back optic zone when there is residual astigmatism present.

Spectacle refraction (vertex distance ignored):

+ 2.50 / − 2.00 × 180

Keratometry reading: 8.04 mm (42.00 D) along 180
7.50 mm (45.00 D) along 90

A rigid spherical trial lens with BOZR 7.95 mm and BVP +1.00 D is placed on the cornea. Refraction with this lens in situ gives +2.00 / −1.00 × 90 and 6 / 6 acuity.

Based on the keratometry readings, BOZR of 8.00 mm and 7.55 mm are chosen to fit the horizontal and vertical meridians respectively.

In this case, residual astigmatism is equal to −1.00 DC × 90. If the patient is to be given the best possible vision it is necessary to incorporate the correction for this residual cylinder into the BVP to be ordered.

The method for determining the BVPs is the same as used in the previous example.

Along 180,

$$\mathrm{BVP}_{\mathrm{CL}} = +\,1.00 + 1.00 - \left(\frac{336}{8.00} - \frac{336}{7.95}\right) = +\,2.25\ \mathrm{D}$$

Along 90,

$$\mathrm{BVP}_{\mathrm{CL}} = +\,1.00 + 2.00 - \left(\frac{336}{7.55} - \frac{336}{7.95}\right) = +\,0.75\ \mathrm{D}$$

The values for the overrefraction are in bold to emphasize the fact that there is residual astigmatism present in this case.

Final Rx of lens:

BOZR 8.00 mm along 180 +2.25 D
BOZR 7.55 mm along 90 +0.75 D

In examples 1 and 2, the powers specified are the BVPs of the toric lens in the appropriate meridians. These are the powers read by the laboratory when checking the lens on a focimeter (vertometer).

It is frequently useful, in considering bitoric lenses, to draw a representation of meridional powers to ensure that simple errors in confusing axes and meridians are not made. Such a power cross is shown in Fig. 16.3.

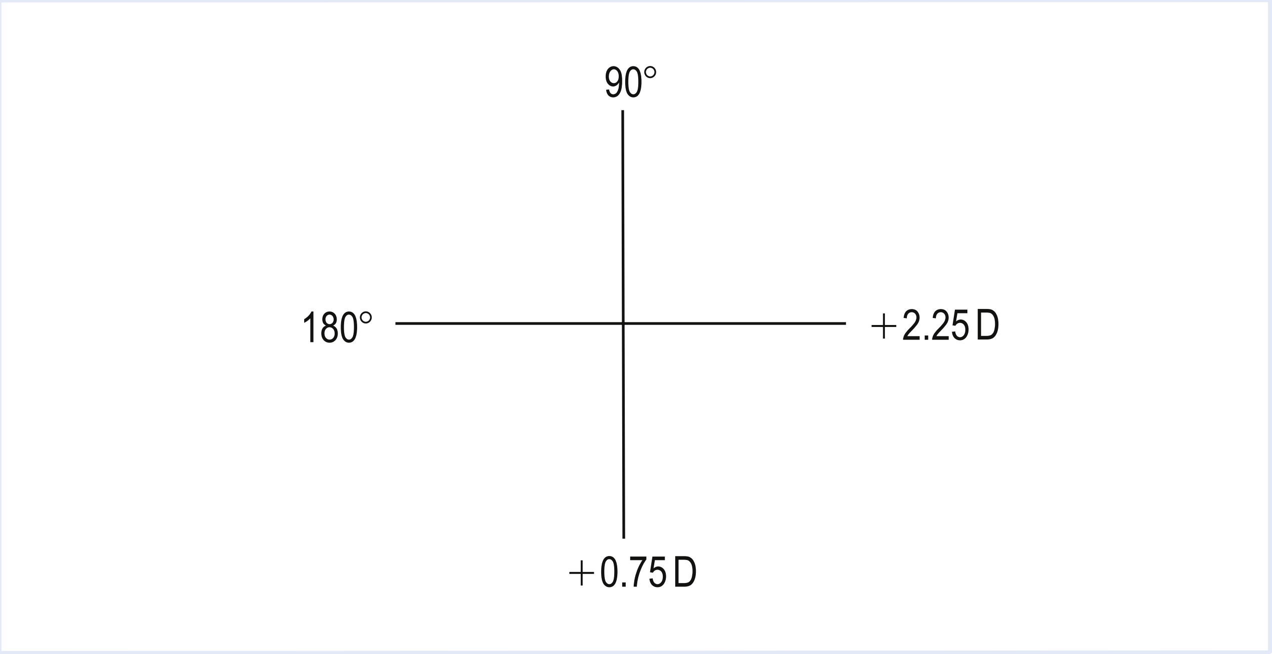

Fig. 16.3 Meridional powers required in Example 2. This shows the powers and directions as they will be measured by the contact lens laboratory.

Sometimes, the axis of the residual astigmatism does not correspond exactly with one of the principal meridians of curvature of the cornea. If the difference between the axes of the spectacle refraction and the principal meridians of the cornea is marginal (less than 20°), one can assume that the axes of the spectacle refraction over the lens do correspond with the principal meridians of corneal curvature. By doing this, the need for any complex oblique cylinder calculations is obviated and the resulting error in the power calculations is usually not significant (Lindsay, 1996). If there is a large difference between the cylinder axis of the ocular refraction and the axis of the corneal astigmatism, then an oblique bitoric lens (where the principal meridians of the toroidal front and back surfaces are not parallel) will be required.

INDUCED ASTIGMATISM

Induced astigmatism is the astigmatic effect created in the contact lens / tear lens system by the toroidal back optic zone bounding two surfaces of different refractive index, namely the lens (refractive index 1.41–1.49 depending on the material) and the tears (refractive index 1.336). As a general rule, rigid lenses with refractive indices lower than 1.458 are made from fluorosilicone acrylates; lenses with refractive indices in the range 1.458–1.469 are made from either fluorosilicone acrylates or silicone acrylates; and lenses with refractive indices greater than 1.469 are made from silicone acrylates (Tranoudis and Efron, 1998).

Consider the lens designed in example 1 with back-surface toric curves of 8.00 mm and 7.55 mm. Assuming a refractive index of 1.47 for the lens material, the surface powers of these curves in air are −58.75 / −62.25, giving a back-surface cylinder of −3.50 DC × 180. On the eye, where the back surface rests against the tear layer (n = 1.336), the powers of the back-surface interface are now −16.75 / −17.75 respectively and the back-surface cylinder in tear fluid is −1.00 DC × 180. This 1.00 D back-surface cylinder ('induced astigmatism') must be compensated by generating a +1.00 D cylinder axis 180 on the front surface (Sarver et al., 1985).

The front-surface cylinder correction for the induced astigmatism is automatically incorporated into the lens prescription when the practitioner calculates the BVPs for the rigid toric lens. Once again, consider the lens designed in Example 1. If a refractive index of 1.47 for the lens material and a lens centre thickness of 0.25 mm is assumed, the required front-surface powers (calculated using thick lens formulae) based on BOZR of 8.00 and 7.55 mm and BVP of +2.25 and −0.25 D would be +60.37/+61.35, respectively. Specification of the appropriate BOZR and BVP therefore results in the front surface incorporating the required compensating cylinder of +1.00 DC × 180.

A quick way to calculate the induced astigmatism is to use the appropriate radii considered with the change from the rigid lens to the tears. That is:

$$\text{Power of the RGP lens/tear boundary} = \frac{1000\,(1.336 - 1.47)}{r} = \frac{-134}{r}$$

where r = radius (in millimetres) and the refractive index of the rigid lens material is assumed to be equal to 1.47.

By subtracting the values found of −134/r for one principal meridian from the other, the value for the induced astigmatism may be obtained directly. With rigid lens materials of refractive index not equal to 1.47, the figure of −134/r no longer applies: for example, a refractive index of 1.45 would yield a figure of 114/r for determining the surface power at the lens/tear boundary.

SPHERICAL POWER EQUIVALENT (‘COMPENSATED’) BITORIC LENSES

These are lenses that, like spherical lenses, do not correct for any residual astigmatism (Sarver, 1963). They are bitoric because the front surface contains a cylinder solely for the correction of the induced astigmatism. The lens designed in Example 1 would be characterized as a compensated bitoric lens.

A compensated bitoric can be thought of as a lens designed to correct all of the refractive cylinder created because of the corneal toricity (Lowther, 1990). If the corneal toricity is equal to the spectacle astigmatism, when a compensated bitoric is placed on the cornea the cylinder will be fully corrected.

A compensated bitoric lens can rotate on the eye without visual disturbance because the effect of the rotation is counteracted by an equal change in the cylinder power of the tear lens.

CYLINDRICAL POWER EQUIVALENT TORIC LENSES

All other types of rigid toric lenses come under this classification, and the unifying feature of these lenses is that they incorporate a correction for residual astigmatism. This type of lens can be further categorized as follows.

Alignment Bitoric Lenses

These are also known as parallel bitoric lenses. Both the front and back surfaces are toroidal. The front surface incorporates correction for residual astigmatism as well as for the induced astigmatism. In addition, the axes of the spectacle refraction over the lens correspond with the principal meridians of corneal curvature, so the correction for the residual astigmatism will be along one of the principal meridians of the lens (hence the name ‘alignment bitoric’). As such, the use of the term ‘alignment bitoric’ here should not be confused with alignment in regard to lens fitting. The lens specified in Example 2 was an alignment bitoric lens.

Back-surface Toric Lenses

These lenses have a toroidal back surface but a spherical front surface. The design principle is similar to that for alignment bitorics. As with alignment bitorics, the front surface incorporates correction for residual astigmatism as well as for the induced astigmatism and the axes of the spectacle refraction over the lens correspond with the principal meridians of corneal curvature, so the correction for the residual astigmatism is along one of the principal meridians of the lens.

In the case of a back-surface toric lens, however, the correction for the residual astigmatism is equal and opposite to the correction for the induced astigmatism. Hence the two required cylindrical corrections cancel each other out, meaning that the front surface can be left spherical.

Very occasionally a case of induced and residual astigmatism cancelling out one another is encountered in practice, as in the following example.

Example 3: Spectacle refraction (vertex distance ignored):

+ 3.00/− 4.00 × 180

Keratometry reading: 8.04 mm (42.00 D) along 180
7.50 mm (45.00 D) along 90

A rigid spherical trial lens with BOZR 7.95 mm and BVP +1.00 D is placed on the cornea. Refraction with this lens in situ gives +1.50/−1.00 × 180 and 6/6 acuity. Hence there is residual astigmatism present, namely −1.00 DC × 180.

Based on the keratometry readings, BOZR of 8.00 mm and 7.55 mm are chosen to fit the horizontal and vertical meridians, respectively.

The induced astigmatism can be determined using the method described previously of calculating the change in power of the RGP lens/tear boundary. By subtracting the values found of −134/r for one principal meridian from the other (assuming a lens refractive index of 1.47), the value for the induced astigmatism is obtained.

$$\text{Induced astigmatism} = \frac{-134}{8.00} - \frac{-134}{7.55} = +1.00\ \text{D}$$

The induced astigmatism, expressed in negative cylinder form, will always have the same axis as the corneal astigmatism. Hence, the induced back-surface cylinder here is −1.00 DC × 180.

The correction for the residual astigmatism is −1.00 DC × 180, so the residual astigmatism and the induced astigmatism should cancel each other out. This can be confirmed by calculation of the BVPs and the front- and back-surface powers of the lens (assuming a lens centre thickness of 0.25 mm).

Along 180,

$$\text{BVP}_{CL} = +1.00 + 1.50 + \left(\frac{336}{7.95} - \frac{336}{8.00}\right) = +2.75\ \text{D}$$

$$\text{Back-surface power of the contact lens} = \frac{1000\ (1 - 1.47)}{+8.00} = 58.75\ \text{D}$$

Front-surface power of the contact lens = + 60.86 D

Along 90,

$$\text{BVP}_{CL} = +1.00 + 0.50 + \left(\frac{336}{7.95} - \frac{336}{7.55}\right) = -0.75\ \text{D}$$

$$\text{Back-surface power of the contact lens} = \frac{1000\,(1 - 1.47)}{+7.55} = -62.25\ \text{D}$$

Front-surface power of the contact lens = + 60.86

The front surface is spherical (same power along both principal meridians) so the residual and induced astigmatism have indeed cancelled each other out. (When calculating surface powers, for clinical purposes a difference in power of ≤0.12 D between the principal meridians constitutes a spherical surface.)

A back-surface toric design is possible only if the correction for the residual astigmatism is equal and opposite to the correction for the induced astigmatism. A back-surface toric design is therefore worth considering only if the ocular astigmatism of the patient is greater than the corneal astigmatism (Meyler and Ruston, 1995). The residual astigmatism must also then be of a magnitude whereby it will be neutralized by the resultant induced astigmatism. The likelihood of both of these requirements being met is low, so in only a small percentage of cases will a back-surface toric design be appropriate. Indeed, in most cases the induced astigmatism usually exaggerates the effect of the residual astigmatism.

Front-surface Toric Lenses

Residual astigmatism frequently needs to be corrected in cases where the patient is fitted well, physically, with a lens utilizing a spherical back optic zone. Such a lens therefore requires a toroidal front surface, but lens rotation must be avoided, otherwise visual disturbance will result. When the corneal astigmatism is less than 2.00 D, a toric back surface will not generally prevent lens rotation and so other forms of lens stabilization, such as prism ballast or truncation, are required.

Prism ballast is the most commonly used method of lens stabilization for rigid lenses that have toroidal front surfaces combined with spherical back optic zones. With prism ballasting, the lens is prescribed in the normal manner with the addition of between 1 and 3^{Δ}. When ordering the lens, practitioners assume that the weight or prism ballast orients the lens in a certain fixed position on the cornea and order the cylinder axis with respect to this position. To avoid recording the prism base position as 'down along 90' or 'down along 100', its actual location is recorded as being at 270 or 280, respectively.

Prism ballast may also be used in combination with a toroidal back surface, where a patient's corneal astigmatism is too small (<2.00 D) to maintain the proper position of a bitoric lens but large enough (>1.00 D) to cause a front toric lens to become unstable (Gonce and Kastl, 1994).

Truncations can also be added to front-surface toric lenses if prism ballasting is insufficient to stabilize the lens. The usual method of designing a truncation for a prism-ballasted lens is to prescribe the lens in the normal way with the addition of the front-surface cylinder at the correct angle relative to the estimated or observed position of the prism base. The relationship of the lower lid to the edge of the lens is observed and a truncation is then cut to align with the lower lid (Fig. 16.4).

Prism ballasting can often cause rigid lenses to sit inferiorly, causing patients to experience symptoms of discomfort and flare. Truncations can also be uncomfortable for the patient and they are not always successful in preventing lens rotation. Consequently, a soft toric contact lens is generally preferred to a rigid toric contact lens when fitting lenses in patients who have significant residual astigmatism but negligible corneal astigmatism.

Oblique Bitoric Lenses

As with alignment bitoric lenses, oblique bitoric lenses have a toroidal front and back surface. With oblique bitorics, however, the principal meridians of the toroidal back and front surfaces are not parallel, owing to a difference between the axes of the spectacle refraction and the principal meridians of corneal curvature. The specification and manufacture of these type of lenses are very difficult. One solution is to use a fitting set of lenses, all of which have a toroidal back optic zone and a spherical front surface. A refraction is performed over the appropriate trial lens and then the oblique cylinder obtained from this refraction is incorporated onto the front surface of the lens. These lenses are rarely prescribed.

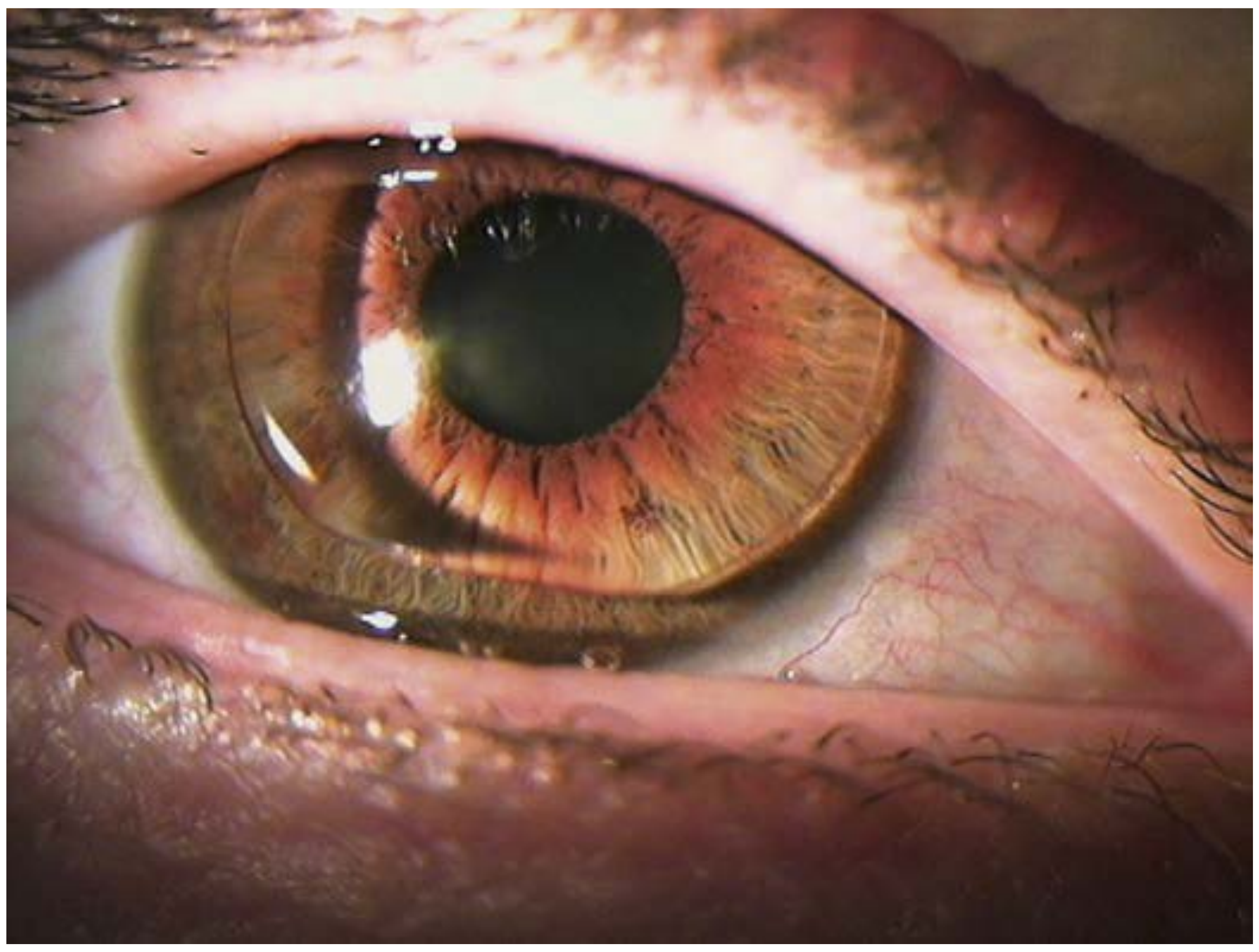
Fig. 16.4 A prism-ballasted rigid toric lens with single truncation. This often proves very successful in preventing unwanted rotation.

EFFECT OF LENS ROTATION

With all cylindrical power equivalent bitoric lenses, some visual disturbance will occur with rotation as the lenses incorporate a correction for residual astigmatism and the axis of correction for the residual astigmatism remains fixed in relation to the eye.

This limitation on rotation is important, for when residual astigmatism is of a low degree from a clinical standpoint then it is not worthwhile incorporating its correction with that for the induced astigmatism. If, however, the residual astigmatism is clinically significant then it is worth incorporating provided that lens rotation can be kept to a minimum (Figs. 16.5 and 16.6).

With lenses incorporating a toroidal back surface, rotation is generally not a problem owing to the stabilizing effect of the toric back surface on the toric cornea (provided there is sufficient corneal toricity).

Conclusion

Advances in soft toric lens technology have resulted in it being the predominant and preferred method of correcting astigmatism, especially when considering the increased chair time required to arrive at a successful rigid toric lens fitting. Nevertheless, there will be occasions when one of the more sophisticated rigid toric lenses is required for a given patient. In fact there is an apparent trend for rigid lenses to be used more for specialist fits, such as sophisticated toric designs, multifocals and orthokeratology (Morgan and Efron, 2008). Blackmore et al. (2006) surveyed diplomates of the American Academy of Optometry,

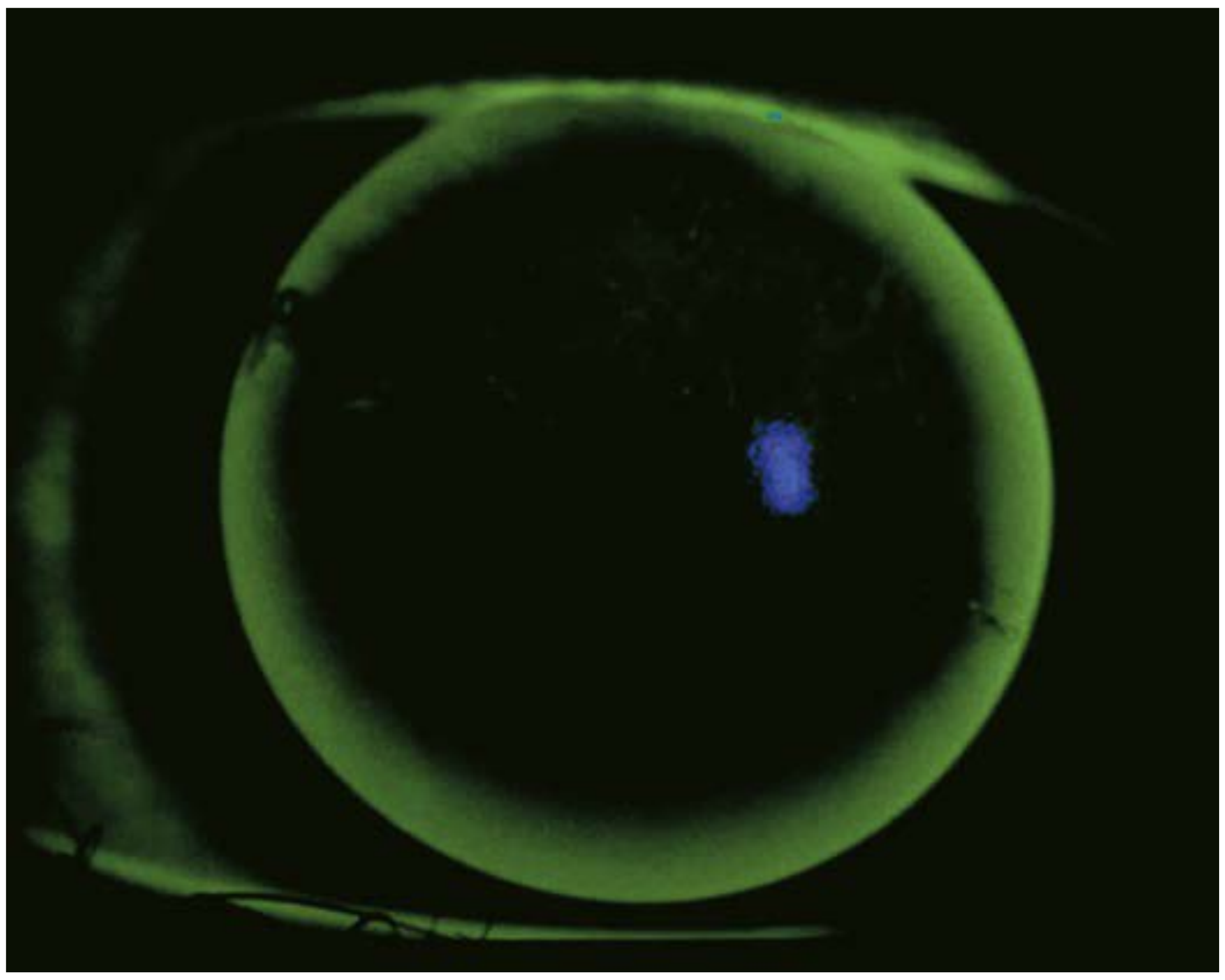

Fig. 16.5 A right lens with a toroidal back optic zone fitted in alignment. Keratometer reading is 8.13 mm along 160 and 7.62 mm along 70. Lens back optic zone radius 8.10 × 7.70 mm. The 8.10 meridian is marked with grease pencil and can be seen aligning well with the 160 meridian. There is no significant rotation, thus permitting accurate correction of residual astigmatism, as well as induced astigmatism, with a front-surface cylinder.

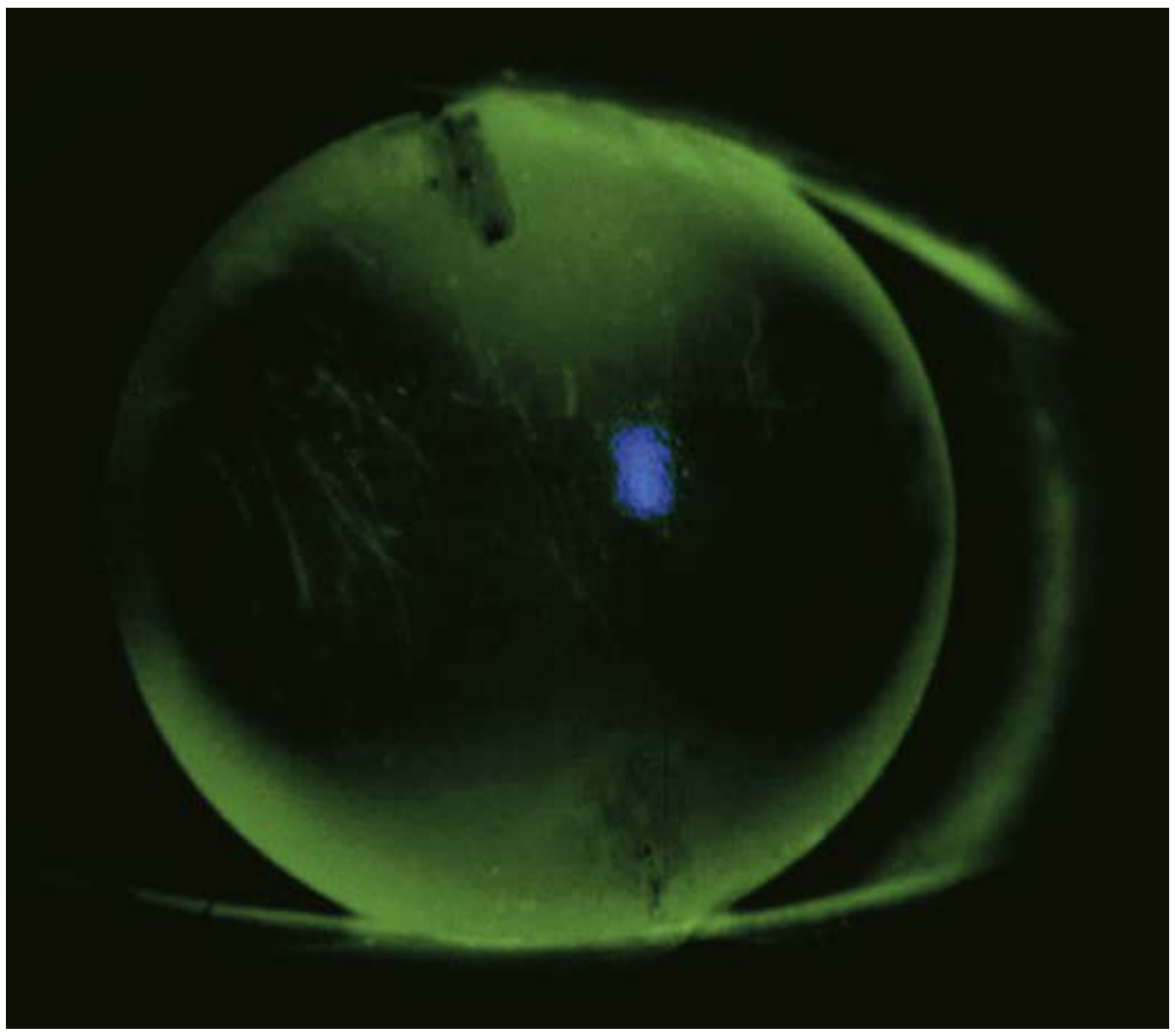

Fig. 16.6 Same right eye as in Fig. 16.5. Lens back optic zone radius 8.05 × 7.75 with 8.05 meridian marked with grease pencil. This should be located along the 160 meridian but, as shown, this lens rotates badly, thus permitting only the accurate correction of induced astigmatism with a front-surface cylinder.

most of whom considered that back-surface toric and bitoric rigid lenses are easy to design and fit. Some practitioners, however, may choose to refer especially challenging cases to a colleague who takes a special interest in rigid toric lens fitting and who has the necessary repertoire of custom-designed trial lens sets. Notwithstanding that possibility, the utility of this chapter is that it provides an overview of the optical considerations and possible lens designs for the various forms of complex astigmatic correction that can sometimes present in practice.

Access the complete references list online at http://www.expertconsult.com.

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17

Rigid Lens Care Systems

PHILIP B MORGAN

Introduction

This chapter reviews the care systems used with rigid contact lenses. Of course, many of the general principles of contact lens care, such as the rationale for lens cleaning and disinfection, regulatory control of the contact lens care industry and various approaches to comparing the efficacy of different solutions, have already been discussed in Chapter 10 and will not be repeated here.

Disinfection and Wetting Solutions

Traditionally, rigid lens products were preserved with benzalkonium chloride, thiomersal and chlorhexidine. However, there is some evidence that sufficient levels of chlorhexidine or benzalkonium chloride can bind to the surface of a rigid lens, leading to a toxic reaction at the ocular surface after lens insertion (Rosenthal et al., 1986). More recent products have seen a move away from these preservative agents or, as in the case of the Boston Advance product, a reduction in chlorhexidine concentration compared with previous care solutions. Also, polyhexanide (more traditionally part of soft lens disinfectant products) has been introduced as a second preservative in rigid lens solutions (Table 17.1). For example, Boston Simplus multi-action solution (Bausch & Lomb) contains polyhexanide as its disinfectant (Fig. 17.1).

Multipurpose solutions for cleaning and disinfecting rigid gas-permeable lenses have replaced single-purpose solutions, but there are few reports of the efficacy of these multipurpose solutions, or of the effects of storage conditions on their disinfecting capacities. Boost et al. (2006) showed that multipurpose solutions for rigid lenses lose activity over the 3 months' recommended time of use but remain satisfactory for use. Disinfecting capacity reduced more quickly when the solution was stored in the refrigerator. Rigid lens disinfecting solutions are not able to kill Acanthamoeba species during manufacturer-recommended disinfection times (Boost et al., 2012).

In addition to their role in lens disinfection, most rigid lens storage solutions also act to wet or to condition the lens. This role is principally to act as a lubricant, affording a degree of protection to the cornea and lid margins when the lens is inserted. The cushioning effect minimizes discomfort at insertion. The secondary effects of successful lens wetting are that the lens surface is, first, rendered hydrophilic to aid a stable pre-lens tear film and, second, made more biocompatible, which might reduce protein deposition.

Various agents are incorporated into rigid lens solutions to aid surface conditioning. Polyvinyl alcohol is a positively charged polymer that is attracted to the negatively charged surface of lenses containing methacrylic acid to provide a more wettable lens (Walker, 1997). Another agent used to increase wettability is the viscosity agent hydroxyethylcellulose. In addition to preservative and conditioning/wetting agents, rigid lens care solutions contain buffering agents to maintain a stable pH, and chelating agents to increase antimicrobial action and assist in lens cleaning.

Cleaning Solutions

Some rigid lenses are cleaned with a separate solution to the disinfectant and wetting product, whereas others follow many of the soft lens care systems and are multipurpose products. Separate rigid lens-cleaning solutions can be more intensive than their soft lens equivalents because there is less opportunity for the solution to enter the lens material, with the subsequent possibility of toxic reaction. For example, Boston Advance Cleaner (Bausch & Lomb) contains a silica suspension of microscopic beads, which act like a gentle polish on the lens; this is beneficial

TABLE 17.1 Constituents of Rigid Lens Disinfecting Solutions

Company	Product	Preservative (ppm)	Surfactant/Conditioner/Viscosity Agents
Abbott Medical Optics	Total Care	Polyhexanide (5)	Hydroxyethyl cellulose
Advanced Eyecare Research	Regard K RGP	Oxychlorite	Pluronic F127 Hydroxypropyl methylcellulose
Alcon	Opti-Free GP	Polyquad (11)	Poloxamine Hydroxypropyl guar
Bausch & Lomb	Boston Advance	Polyhexanide (5) Chlorhexidine (30)	Polyquaternium 10 Polyvinyl alcohol Derivatized polyethylene glycol Cellulose viscosifer
Bausch & Lomb	Boston Simplus	Polyhexanide (5) Chlorhexidine (30)	Poloxamine Hydroxypropyl methylcellulose
Menicon	Unique pH	Polyquad (11)	Poloxamine Hydroxypropyl guar

Total Care
Total Care
Bausch & Lomb
Boston
Boston
Boston
SIMPLUS
Regard
RGP

Fig. 17.1 Care systems for rigid lenses. (Courtesy of Abbott, Bausch & Lomb, and Advanced Eyecare.)

with deposits such as denatured proteins, which can otherwise be difficult to remove. This cleaner also contains an alcohol base, which assists in removing lipid-type spoilation.

Protein Removal Solutions

Protein removal is arguably more important with rigid lenses than with soft lenses, in view of the fact that most soft lenses prescribed today are replaced more regularly than rigid lenses. With few exceptions, protein removal systems that were originally designed for use with soft lenses can also be used with rigid lenses. The frequency with which patients should be advised to use protein removal systems, and how such systems should be applied to the lenses, will vary depending on the lens material and the strength of the active ingredient in the protein removal system. Advice on these issues should be obtained from the manufacturer.

Individual patient factors will also have an impact on the way protein removal systems should be applied. Patients who display a propensity for depositing protein on lenses, and who wear their lenses more frequently and for longer periods of time, may need to treat their lenses more regularly. Typical frequencies of usage of protein removal systems vary from weekly to monthly.

Disinfection of Trial Lens Sets

Proper application of the standard lens care protocols described in this chapter will be efficacious at killing most bacteria, viruses, fungi and protozoa, especially those known to cause infection in the eye. However, certain infectious agents have more recently been identified that are apparently resistant to current soft and rigid lens care regimens. Of particular concern is a proteinaceous vector known as a prion – a chameleon-like infectious agent that exists in different strains that have distinct biological properties and can alter when the disease for which it is responsible crosses the species barrier. It has been suggested by health authorities in the UK that there is a remote theoretical risk of transmission of variant Creutzfeldt–Jacob disease (vCJD) between humans, via transfer of bodily tissues and fluids such as tears.

An extension of the above argument leads to the conclusion that vCJD could theoretically be transmitted from an infected individual to another person via a trial contact lens contaminated with the offending prion. Although such transmission is theoretically possible, it remains highly improbable (Armstrong, 2006). In the light of this, the College of Optometrists recommends that single-use trial lenses should be used whenever possible to limit any chance of disease transmission. Indeed, excellent success rates in fitting rigid lenses empirically (i.e. the lens is ordered based on measures of refraction and ocular dimensions) have been demonstrated. However, it is recognized that in certain cases, particularly where there is disease or abnormality of the lid, cornea or ocular surface, special complex diagnostic contact lenses may be necessary for a successful clinical outcome. These lenses may need to be reused. An obvious case is keratoconus, as a practitioner who fits patients with this condition may have access to a number of trial fitting sets, each representing a different design philosophy.

Where empirical fitting is impracticable then suitable items should be decontaminated using a recognized method. Comoy et al. (2003) found that Menicon Progent and Menicon MeniLAB (0.4 and 0.5% sodium hypochlorite respectively) decreased the infectivity of prions retained on the surface of experimentally contaminated lenses by a factor of at least 10 million. Current advice, however, is to use a readily available sodium hypochlorite 1% solution (10 000 ppm available chlorine), such as is sold for household use, allowing the lens to be safely reused. Macalister and Buckley (2002) concluded that sodium hypochlorite does not appear to distort rigid lenses; however, it may not be used on soft lenses.

Conclusion

Multipurpose care systems are becoming the norm for the maintenance of rigid contact lenses. Because rigid lenses typically have a life span in excess of 6 months, occasional use of protein removal systems may be required. The reuse of rigid trial lenses to determine the best lens fit should be minimized because of the remote theoretical risk of transmission of diseases by agents such as prions, which are resistant to conventional antimicrobial methods. Sodium hypochlorite solution is an effective rigid lens disinfecting solution with antiprion activity.

ACKNOWLEDGEMENT

The author acknowledges the assistance of Kayleigh Walda for photography in Figure 17.1.

Access the complete references list online at http://www.expertconsult.com.

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PART 4

Lens Replacement Modalities

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18

Daily Disposable Soft Lenses

NATHAN EFRON

Introduction

Daily disposable lenses are one of the two versions of true, single-use-only, contact lenses – the other being extended-wear lenses.

Daily disposable lenses first became available in 1994. The Premier daily disposable lens was launched in the UK (later this was sold to Bausch & Lomb) and Johnson & Johnson released the 1-Day Acuvue daily disposable lens into western regions of the USA at around the same time (Meyler and Ruston, 2006). Since their release in the mid 1990s, daily disposable lenses rapidly gained worldwide acceptance. This trend has continued into the 21st century, as indicated in Fig. 18.1, which illustrates the extent of daily disposable lens prescribing as a percentage of all soft lenses fitted in seven nations between 2000 and 2015 (Morgan et al., 2016).

Numerous brands of daily disposable hydrogel lenses have entered the market over the past two decades, and in 2015, the four major global contact lens companies produced 11 brands of spherical, six brands of toric, six brands of multifocal and three brands of cosmetic coloured daily disposable lenses, in both hydrogel and silicone hydrogel materials (Table 18.1) (Kerr and McParland, 2015).

Usage of daily disposable lenses varies widely among nations, as shown in Fig. 18.2. In 2015, daily disposable lenses represented over 50% of all soft contact lenses prescribed in six nations (Australia, Denmark, Italy, Japan, Taiwan and the United Kingdom) (Morgan et al., 2016).

The reasons for the discrepancy in the extent of daily disposable lens prescribing between countries may relate to a number of factors, such as differences in the retail cost to lens wearers, profit margins enjoyed by practitioners, extent and effectiveness of distribution and marketing, and the local influence of opinion leaders. Cost of product is perhaps the most significant factor. It has been demonstrated that in two markets – Australia (Efron et al., 2010) and the United Kingdom (Efron et al., 2012) – the annual cost of wearing daily disposable lenses on a full-time basis is greater than that for reusable lenses, irrespective of lens design (i.e. spherical, toric and multifocal). Although daily disposable lenses are more cost-effective compared with reusable lenses when worn on a part-time basis, it is likely that the overall prescribing of daily disposable lenses is driven by the perceived costs incurred for full-time wear.

Efron et al. (2013) reported that the proportion of daily disposable lens fits (as a function of all soft lens fits) was positively related to the gross domestic product at purchasing parity per capita for year 2011 ($r^2 = 0.55$, $F = 46.8$, $p < 0.0001$) (Fig. 18.3). Inspection of Fig. 18.3 reveals Qatar to be a significant outlier; significant outliers such as this have the potential to exaggerate estimates of correlation. To test whether this was the case, Efron et al. (2013) conducted another linear regression analysis excluding Qatar. This still resulted in a strong correlation ($r^2 = 0.43$, $F = 27.3$, $p < 0.0001$).

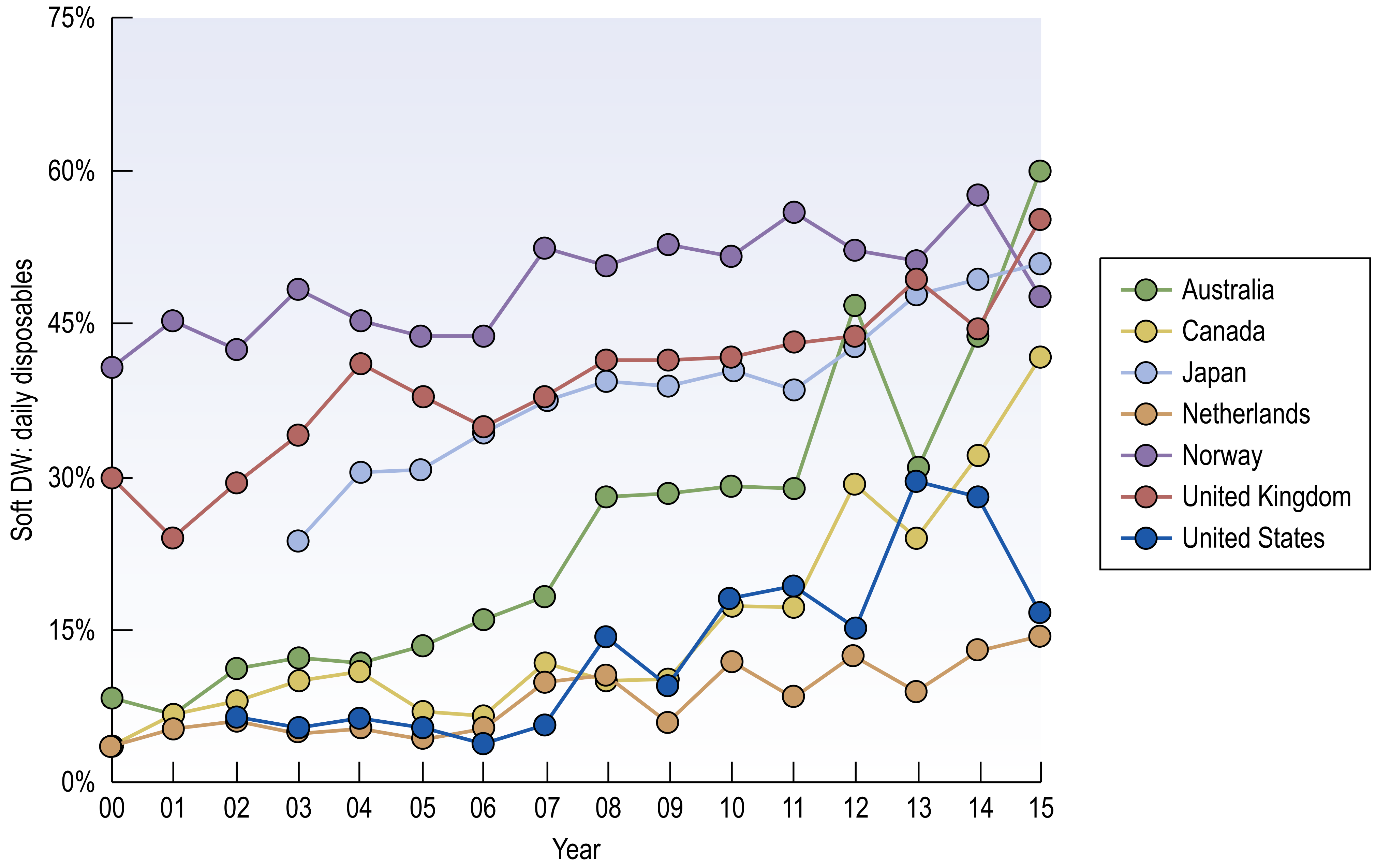

Fig. 18.1 Daily disposable contact lens fits as a proportion of all soft lens fits between 2000 and 2015 in seven nations.

TABLE 18.1 Daily Disposable Contact Lenses

Lens Brand	Manufacturer	Material	Water Content (%)	BOZR[a] (mm)	Diameter (mm)
SPHERICAL – HYDROGEL					
Focus Dailies AquaComfort Plus	Alcon	Nelfilcon A II 2	69	8.7	14.0
Focus Dailies All Day Comfort	Alcon	Nelfilcon A II 2	69	8.6	13.8
Biotrue One Day	Bausch & Lomb	Nesofilcon A	78	8.6	14.2
SofLens Daily Disposable	Bausch & Lomb	Hilafilcon B II 2	59	8.6	14.2
BioMedics 1 Day Extra	CooperVision	Ocufilcon D IV 1	55	8.6/8.8	14.2
Proclear 1 Day	CooperVision	Omafilcon A II 2	60	8.7	14.2
1-Day Acuvue Moist	Johnson & Johnson	Etafilcon A IV 2	58	8.5, 9.0	14.2
SPHERICAL – SILICONE HYDROGEL					
Dailies Total 1	Alcon	Delefilcon A	30/80[b]	8.5	14.1
Clariti 1 day	CooperVision	Somofilcon A	56	8.6	14.1
MyDay	CooperVision	Stenfilcon A	54	8.4	14.2
1-Day Acuvue TruEye	Johnson & Johnson	Narafilcon A I 4	46	8.5, 9.0	14.2
TORIC – HYDROGEL					
Focus Dailies AquaComfort Plus Toric	Alcon	Nelfilcon A II 2	69	8.8	14.4
Focus Dailies All Day Comfort Toric	Alcon	Nelfilcon A II 2	69	8.6	14.2
SofLens Daily Disposable Toric for Astigmatism	Bausch & Lomb	Hilafilcon B II 2	59	8.6	14.2
BioMedics 1 Day Extra Toric	CooperVision	Ocufilcon D IV 1	55	8.7	14.5
1-Day Acuvue Moist for Astigmatism	Johnson & Johnson	Etafilcon A IV 2	58	8.5	14.5
TORIC – SILICONE HYDROGEL					
Clariti 1 day toric	CooperVision	Somofilcon A	56	8.6	14.3
MULTIFOCAL – HYDROGEL					
Focus Dailies AquaComfort Plus Multifocal	Alcon	Nelfilcon A II 2	69	8.7	14.0
Focus Dailies All Day Comfort Progressives	Alcon	Nelfilcon A II 2	69	8.6	13.8
Biotrue One Day for Presbyopia	Bausch & Lomb	Nesofilcon A	78	8.6	14.2
Proclear 1 Day Multifocal	CooperVision	Omafilcon A II 2	60	8.7	14.2
1-Day Acuvue Moist Multifocal	Johnson & Johnson	Etafilcon A IV 2	58	8.4	14.3
MULTIFOCAL – SILICONE HYDROGEL					
Clariti 1 day multifocal	CooperVision	Somofilcon A	56	8.6	14.1
COSMETIC – HYDROGEL					
FreshLook Illuminate[c]	Alcon	Nelfilcon A II 2	69	8.6	13.8
FreshLook One-Day[d]	Alcon	Nelfilcon A II 2	69	8.6	13.8
1-Day Acuvue Define[e]	Johnson & Johnson	Etafilcon A IV 2	58	8.5	14.2

[a] BOZR = back optical zone radius.
[b] Core water content 30%; surface water content 80%
[c] Dark limbal ring pattern.
[d] Available in blue, green, grey and hazel.
[e] Limbal ring available in 'natural sparkle' and 'natural shimmer'.

The demonstration of a strong relationship between the extent of daily disposable lens fitting and the gross domestic product at purchasing parity per capita (essentially a measure of the average wealth of individuals in a nation) supports the hypothesis that the extent of daily disposable lens prescribing is driven to a large extent by cost considerations. Indeed, over half of the variance in daily disposable prescribing between nations can be explained by the gross domestic product at purchasing parity per capita.

Patterns of Wear

The influence of contact lens type on wearing frequency was investigated by Efron and Morgan (2009). All daily-wear lenses were categorized into three groups: rigid, soft daily disposable and 'soft other'. The latter group comprises all reusable (non-daily disposable) soft lenses. The proportion of all fits in relation to the number of days lenses are worn each week is shown in Fig. 18.4 for each of these three categories. For rigid and 'soft other' lenses, there is an increasing proportion of fits being used for a greater number of days each week; this distribution is more sharply skewed in respect of rigid lens wearers. The distribution for daily disposable lens wearers appears to be bimodal, with peak wearing frequencies at 2 and 7 days per week. Soft daily disposable lenses are worn, on average, 3.5 ± 2.0 days per week. If part-time and full-time wear is defined as lenses being worn 1–3 and 4–7 days per week, respectively, 40% of those fitted with daily disposable lenses wear lenses full-time versus 91% of those using 'other soft' lenses.

Dumbleton et al. (2013) surveyed lens-wearing patterns in Australia, Norway, the United Kingdom and the United States and reported that, overall, 59% of participants reported wearing their lenses for 7 days per week. A significantly higher proportion of participants reported wearing lenses 7 days per week in the United States and Norway (64% and 71%, respectively) than in Australia and the United Kingdom (35% and 41%, respectively; $p < 0.001$).

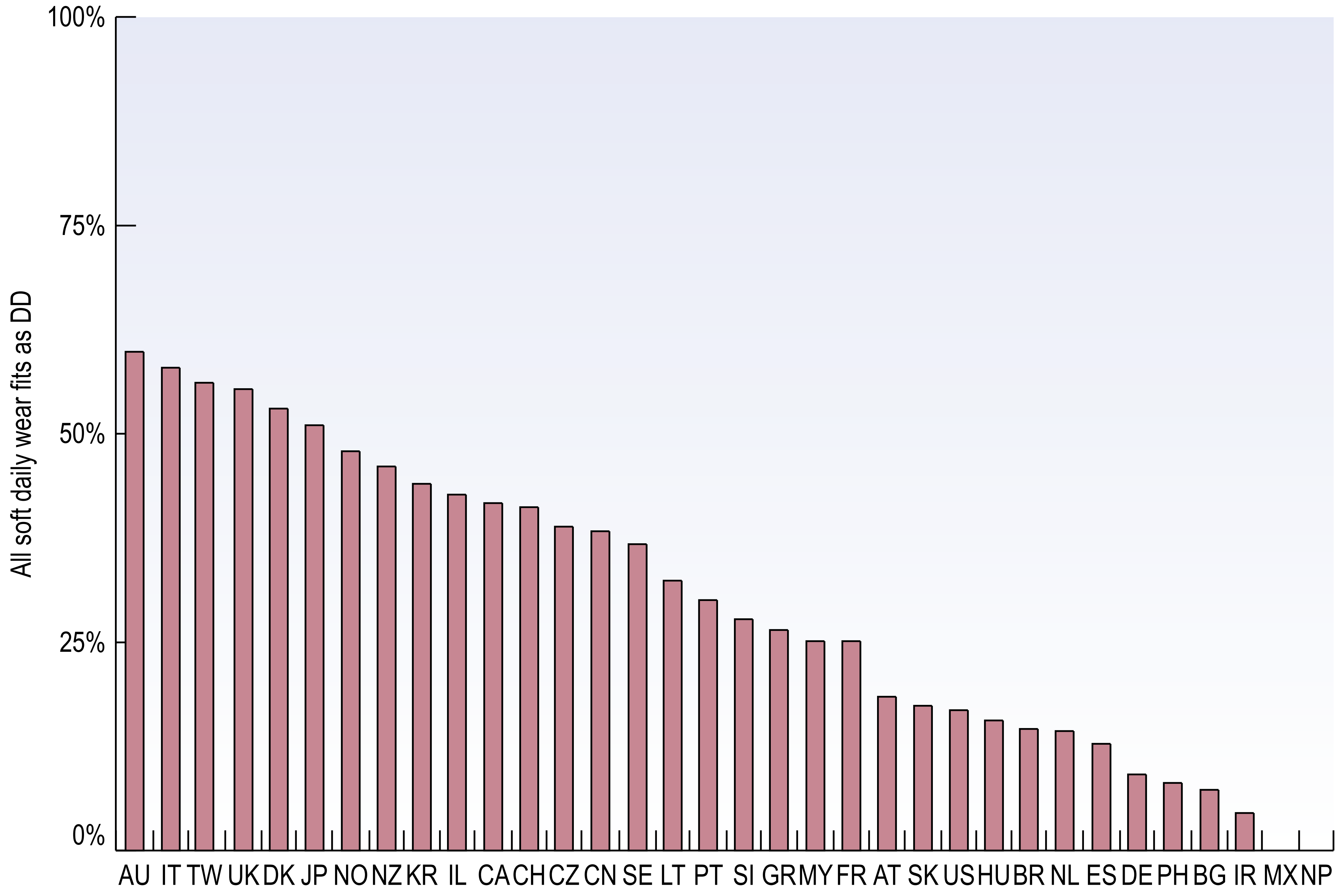

Fig. 18.2 Daily disposable contact lens fits as a proportion of all lens fits in 34 nations in 2015. Country codes: AT = Austria; AU = Australia; BG = Bulgaria; BR = Brazil; CA = Canada; CH = Switzerland; CN = China; CZ = Czech Republic; DE = Germany; DK = Denmark; ES = Spain; FR = France; GR = Greece; HU = Hungary; IL = Israel; IR = Iran; IT = Italy; JP = Japan; KR = Korea; LT = Lithuania; MX = Mexico; MY = Malaysia; NL = Netherlands; NO = Norway; NP = Nepal; NZ = New Zealand; PH = Philippines; PT = Portugal; SE = Sweden; SI = Slovenia; SK = Slovakia; TW = Taiwan; UK = United Kingdom; US = United States.

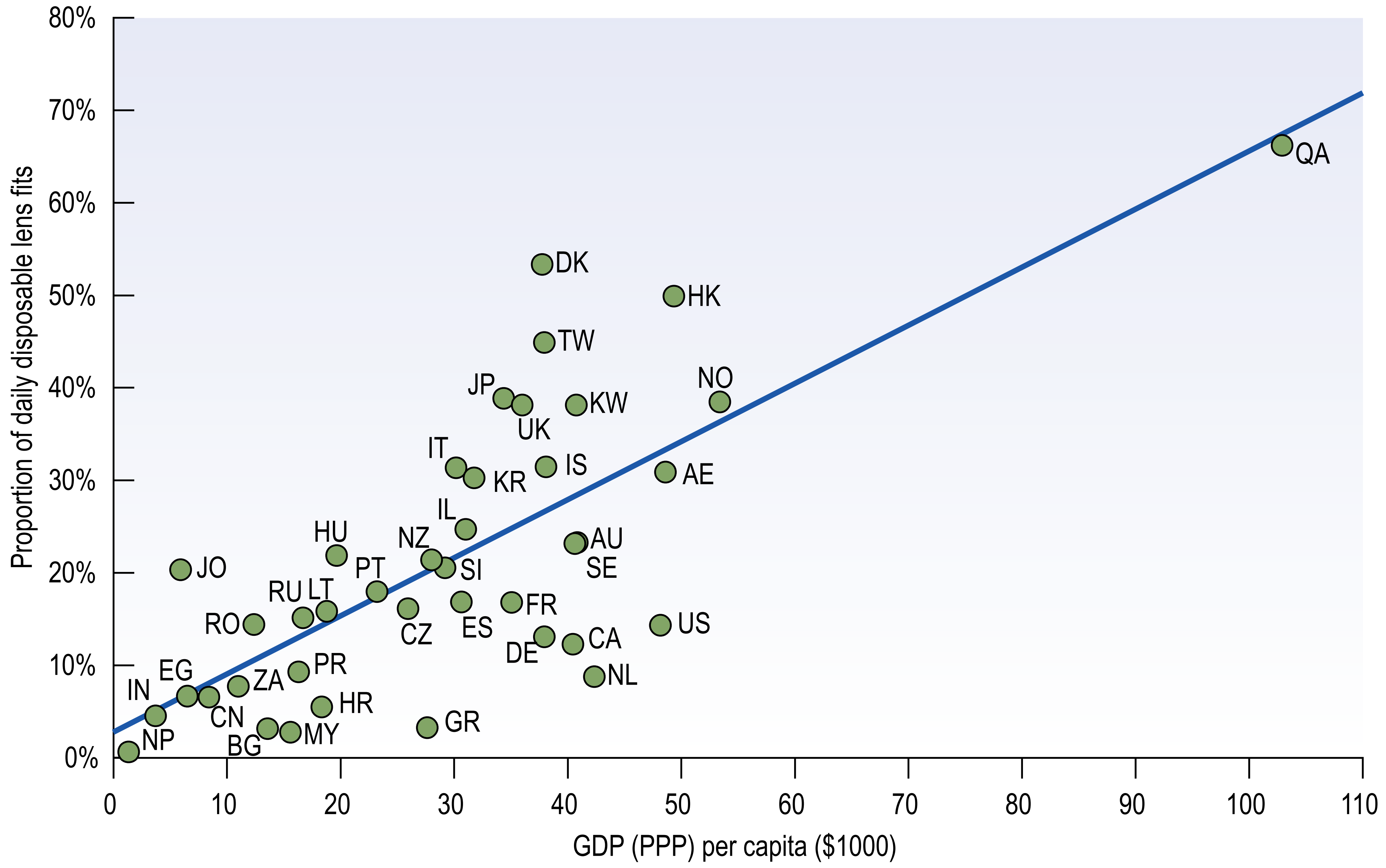

Fig. 18.3 Relation between daily disposable lens fits (as a proportion of all soft lens fits) and the gross domestic product at purchasing parity per capita for year 2011. Country codes: AE = United Arab Emirates; AU = Australia; BG = Bulgaria; CA = Canada; CN = China; CZ = Czech Republic; DE = Germany; DK = Denmark; EG = Egypt; ES = Spain; FR = France; GR = Greece; HK = Hong Kong; HR = Croatia; HU = Hungary; IL = Israel; IN = India; IS = Iceland; IT = Italy; JO = Jordan; JP = Japan; KR = South Korea; KW = Kuwait; LT = Lithuania; MY = Malaysia; NL = Netherlands; NO = Norway; NP = Nepal; NZ = New Zealand; PR = Puerto Rico; PT = Portugal; QA = Qatar; RO = Romania; RU = Russia; SE = Sweden; SI = Slovenia; TW = Taiwan; UK = United Kingdom; US = United States; ZA = South Africa.

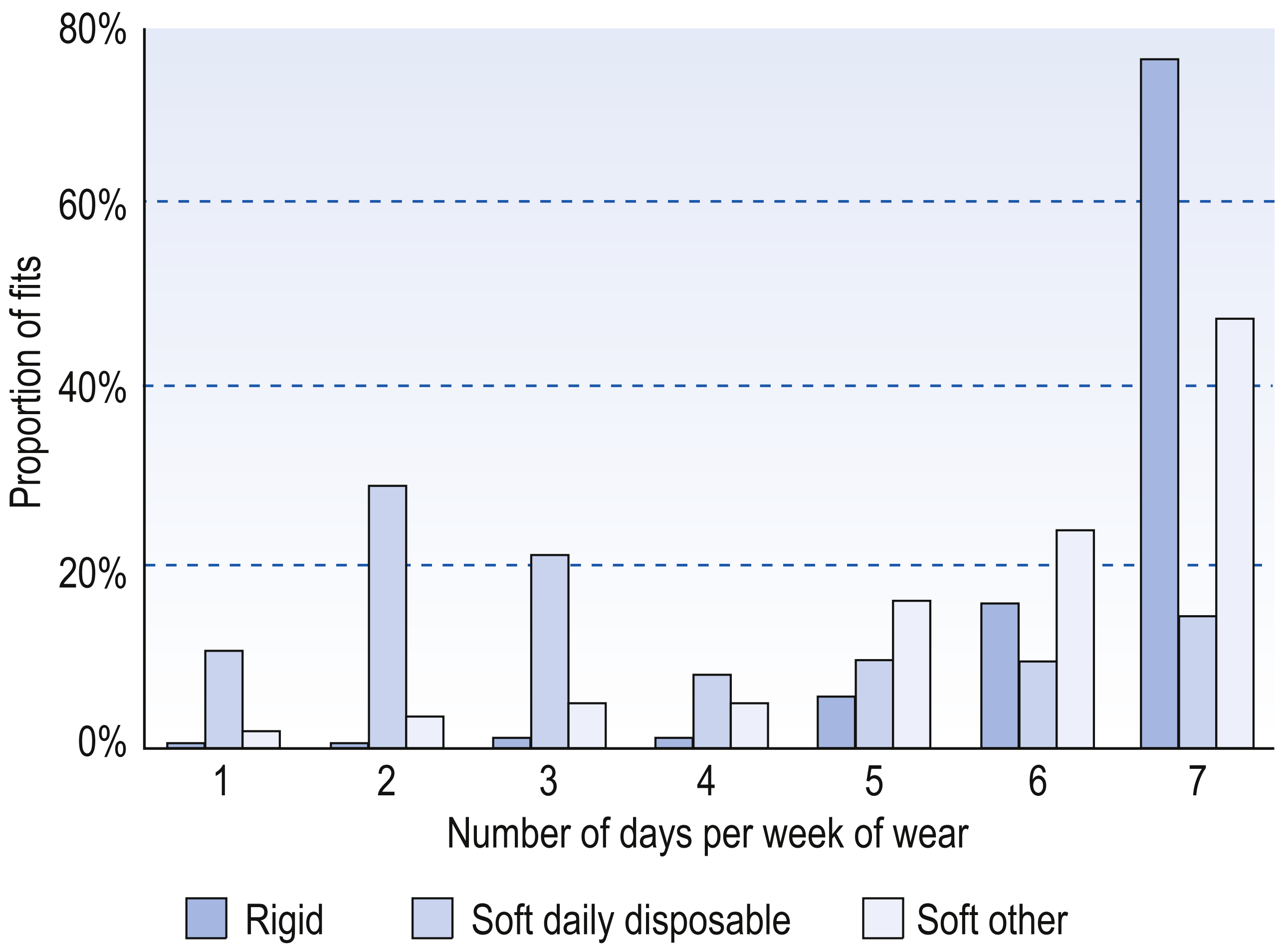

Fig. 18.4 Proportion of rigid, daily disposable soft, and all other soft lenses that are worn for between 1 and 7 days per week.

The bimodal distribution of daily disposable lens wearing frequency shown in Fig. 18.4 may reflect two distinct approaches to lens wear. The peak around 1–3 days per week self-evidently represents those using daily disposable lenses on a part-time basis. Indeed, daily disposable lenses are a logical choice for part-time wear because of increased convenience and enhanced safety, as discussed below. Full-time wear of daily disposable lenses is an expensive option compared with full-time wear of 2-weekly or monthly disposable lenses, and those who wear daily disposable lenses full-time (wearing lenses 4–7 days per week) have presumably determined that the enhanced safety and convenience of this approach are worth the higher cost.

Clinical Performance

If the clinical benefits of planned replacement are accepted, then it would seem logical to change lenses as often as possible. Soon after daily disposable lenses entered the market in the mid 1990s, the benefits of this replacement modality compared with the reusable and non-planned replacement lenses prescribed prior to this time were stark. For example, Solomon et al. (1996) reported that daily disposable lens wearers had fewer symptoms, fewer deposits, better vision, fewer tarsal abnormalities, fewer ocular complications and better overall satisfaction than patients using conventional lenses. Jones et al. (1996) found that lens comfort, subjective symptoms (i.e. dryness, soreness, scratchiness) and vision were significantly better with daily disposable lenses compared with the previously used lens replacement modality (42% of patients were previously using monthly or fortnightly replacement). Hamano et al. (1994) observed a 4.9% incidence of complications for daily disposable lens wearers compared with 8.5% for conventional daily-wear soft lens wearers. In a comparison of 2-weekly with daily disposability lenses, Sindt (2000) noted that, at the very least, patients wearing single-use lenses benefited from greater convenience and comfort.

Contemporary studies show similar benefits (Cho and Boost, 2013). An extensive evaluation of the ocular response to neophyte patients fitted with one brand of silicone hydrogel daily disposable lenses (Acuvue TruEye, Johnson & Johnson Vision Care) demonstrated excellent comfort and vision with minimal alterations to ocular physiology (Morgan et al., 2013). Diec et al. (2012) also noted good subjective and objective responses to daily disposable lenses, but observed that different contact lens materials and designs elicited different ocular and patient responses.

Ichijima et al. (2016) demonstrated that when patients switched to daily disposable lenses after having used 2-weekly replacement lenses there was a reduction in subjective complaints of dryness, and objectively a significant reduction of superficial punctate keratitis was observed at follow-up examinations.

Wolffsohn et al. (2015) assessed the influence of end-of-day silicone hydrogel daily disposable contact lens fit on ocular comfort, physiology and lens wettability. Among the three lenses tested, objective lens fit changed between 8 and 12 hours of lens wear. The authors suggested that the weak correlation in individual lens fit between brands indicates that fit is dependent on more than ocular shape. Consequently, substitution of a different lens brand with similar parameters will not necessarily provide a comparable lens fit.

Varikooty et al. (2015) compared the clinical performance of three silicone hydrogel daily disposable lenses and found that they all performed well, with only slight differences in physiological responses between lenses. They found no difference between asymptomatic and symptomatic wearers with regard to ocular response and contact lens-related parameters, and concluded that silicone hydrogel daily disposable lenses are an excellent contact lens modality for the symptomatic patient.

The obvious advantage offered by daily lens disposal is a fresh, sterile pair of lenses for wearing each day. If cost was not a limiting factor, then it could be argued that all daily-wear soft lens patients should be using this modality.

Advantages from the Perspective of Practitioners

Specific advantages of daily disposable lenses from the standpoint of the practitioner include the following:

- Less patient education time is required (virtually no advice needs to be given about lens care).
- The absence of a lens storage case from the regimen is beneficial, given the role that a lens case can play in the development of corneal infiltrative events and ocular infection (Richdale et al., 2016).
- Less professional 'chair time' is required because there are no problems relating to lens care solutions (e.g. toxicity or sensitivity reactions) (Richdale et al., 2016) and fewer ocular complications of lens wear compared with that experienced with reusable lenses (Hickson-Curran et al., 2014).
- Less ancillary staff time is required because there is no need for discussions and sales relating to lens care products.
- There are no disputes concerning wearing frequency (e.g. some patients might argue that a lens designed for monthly replacement, but only worn once a week, can last for 3 months).
- Daily disposability is more hygienic for intermittent wearers, as long-term storage problems are eliminated, making daily disposability the replacement modality of choice for such patients.
- The regular supply of large numbers of lenses required for daily lens disposal can be leveraged from a practice management standpoint by introducing strategies such as

monthly payment plans (Patel et al., 2015) and subscriber membership systems (Ichijima et al., 2016), which are considered to be attractive business models and practice builders (Patel et al., 2015).

Advantages from the Perspective of Lens Wearers

Advantages of daily disposable lenses from the perspective of lens wearers include:

- There is no need to be concerned with lens care systems, although it is desirable for daily disposable lens wearers to have a supply of sterile saline or multipurpose solution for lens rinsing if there is discomfort during, or soon after, lens insertion.
- There are no anxieties about lost or damaged lenses.
- Daily disposable lenses are convenient and compact for travel; there is no need to carry bulky lens care solutions.
- Daily disposable lenses are highly cost-effective in that lens wear is directly linked to lens cost (unlike, say, monthly disposable lenses that may be worn only a few times during the month).
- Daily disposable lenses are excellent for monovision correction of presbyopia, as it is easy to alternate between various lens combinations (e.g. two distance lenses versus monovision, depending on the need; see Chapter 23).
- Daily disposable lenses are easy to discard ('any time, any place, without a case').
- Visual performance remains good throughout the day (Belda-Salmerón et al., 2013).
- Compliance is easier because there are fewer instructions to remember (Morgan et al., 2011).

Since daily disposable contact lenses eliminate the need for cleaning and disinfection, they should be strongly considered as a contact lens treatment option for children. Walline et al. (2004) demonstrated that 8–11-year-old children are able to care for daily disposable contact lenses independently and wear them successfully. Plowright et al. (2105) reported similar findings for children aged 13–19. Certainly, Efron et al. (2010) observed that children aged 6–12 years are fitted with the highest proportion of daily disposable lenses, and have the highest rate of fits for part-time wear, compared with infants, teenagers and adults (Efron et al., 2011).

Disadvantages

Potential disadvantages of daily disposable lenses include the following:

- Patients may be non-compliant by way of reusing lenses. Dumbleton et al. (2010) reported that, of patients who were given correct instructions, 12% and 13% reused their daily disposable lenses in the United States and Canada, respectively. Reuse of lenses poses an important risk for daily disposable lens users because they are unlikely to have received proper training in cleaning and disinfection of lenses and do not use a lens case or disinfecting solutions (Boost et al., 2011).
- Practitioners have been known to sanction patients to reuse daily disposable lenses. According to Dumbleton et al. (2010), 4% and 6% of practitioners in the United States and Canada, respectively, recommended that their patients reuse daily disposable lenses.
- New daily disposable lens wearers who have not previously worn other lens types – and have thus never been instructed in lens care – may adopt unwise practices through ignorance (e.g. storing a lens overnight in tap water).
- Because of the low unit cost of lenses, patients may think it is all right to give lenses to friends to try.

Comfort Enhancement Strategies

A number of strategies have been adopted by different manufacturers to enhance the comfort of daily disposable lenses. For example, Alcon has modified Dailies All Day Comfort lenses to include additional, non-functional, polyvinyl alcohol (PVA). PVA is a successful tear film stabilizer and is widely used in comfort drops. According to Peterson et al. (2006), release of additional non-functionalized PVA appears to enhance comfortable contact lens wear. Dailies AquaComfort Plus lenses contain hypromellose (short for hydroxypropyl methylcellulose, or HPMC), polyethylene glycol (PEG) and dual-molecular-weight PVA, as comfort-enhancing agents; such strategies have been shown to be clinically effective in enhancing comfort (Fahmy et al., 2010).

Vistakon have incorporated proprietary wetting agents into their daily disposable lenses. 1-Day Acuvue Moist contains Lacreon, and Acuvue TruEye contains Hydraclear, although the detailed chemical formulations of these agents are not in the public domain.

The use of daily disposable lenses has been shown to be an effective strategy for managing allergy-suffering contact lens wearers. Hayes et al. (2003) monitored subjective comfort and slit-lamp findings with daily disposable contact lenses in a population of allergy sufferers during periods when allergen levels were elevated. Sixty-seven per cent of subjects agreed that the daily disposable lenses provided improved comfort when compared with the lenses they wore prior to the study, versus 18% agreeing that the new pair of habitual lenses provided improved comfort. The daily disposable lenses also resulted in a greater improvement in slit-lamp findings from baseline than new habitual lenses.

Manufacturing Reliability

Efron et al. (1999) examined 150 −3.00 D lenses of each of the first three brands of daily disposable lenses on the market, and reported an overall high degree of accuracy and reproducibility (Fig. 18.5). They found that, with one inconsequential exception, all measured parameters of all three lens types examined fell well within clinically acceptable limits for providing wearers of these lenses with consistent vision and fit.

Each of the currently marketed daily disposable soft lenses is available only in a single diameter. However, diameter is an important parameter in relation to optimizing lens fit. Young (2008) measured the diameters of 13 designs of daily disposable lenses at room and eye temperature. He observed that lenses labelled 14.2 mm ranged in diameter from 13.5 to 14.1 mm when measured at eye temperature. The three lenses showing the greatest shrinkage when raised to eye temperature were all Food and Drug Administration group IV lenses. Young (2008) concluded that comparing labelled diameters is unhelpful, and in some cases misleading, for predicting the on-eye performance of current daily disposable soft lenses.

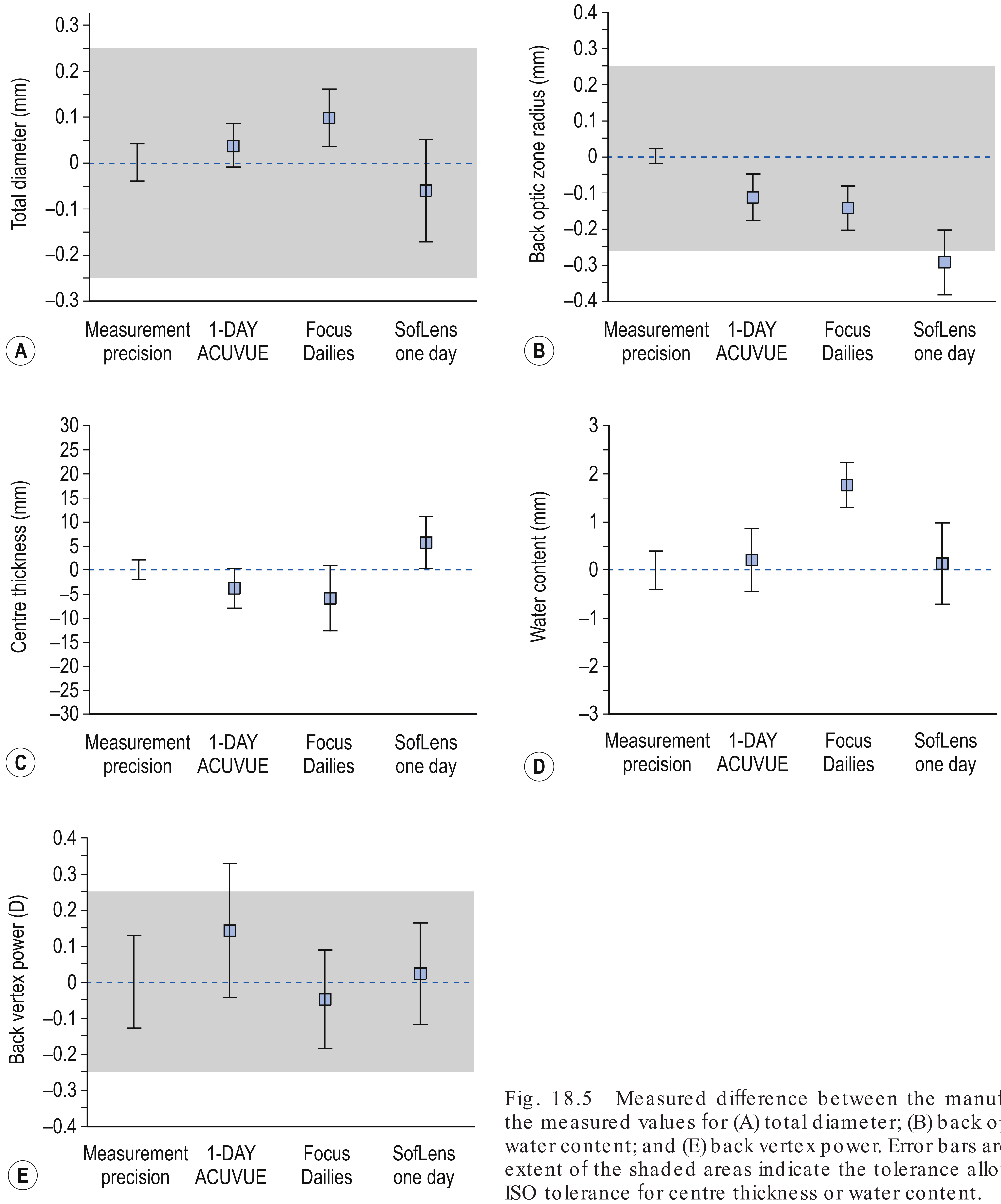

Fig. 18.5 Measured difference between the manufacturers' specification and the mean of the measured values for (A) total diameter; (B) back optic zone radius; (C) centre thickness; (D) water content; and (E) back vertex power. Error bars are mean ± standard deviation. The vertical extent of the shaded areas indicate the tolerance allowed under ISO 8321-2 (1995). There is no ISO tolerance for centre thickness or water content.

Environmental Impact

Concerns that daily disposability will have a greater adverse environmental impact compared with other replacement modalities – with respect to disposal of the lenses and associated packaging – have been dispelled by Morgan et al. (2003). These authors measured the annual wastage involved in the use of unplanned, monthly and daily replacement systems. Specifically, the amount of waste glass, plastic, metal and paper was determined (solutions were ignored because they have a negligible environmental impact) (Fig. 18.6). Of the three replacement systems studied, unplanned lens replacement was found to have the highest environmental impact and monthly lens replacement had the lowest environmental impact. It is possible that the levels of wastage in contact lens manufacture might be more significant than those incurred by consumers. From a wider perspective, the environmental impact of wastage in the use of contact lenses and care systems by consumers pales into insignificance when considered against major sources of world environmental pollution (e.g. road construction, general domestic wastage).

Limitations to More General Acceptance

Notwithstanding their current popularity, there appear to be four main reasons why daily disposable lenses are not even more widely used:

1. Parameter and material limitations – this factor is diminishing as volumes increase and more manufacturers launch daily disposable lenses in wider power ranges, with toric, multifocal, cosmetically coloured and silicone hydrogel lenses available.

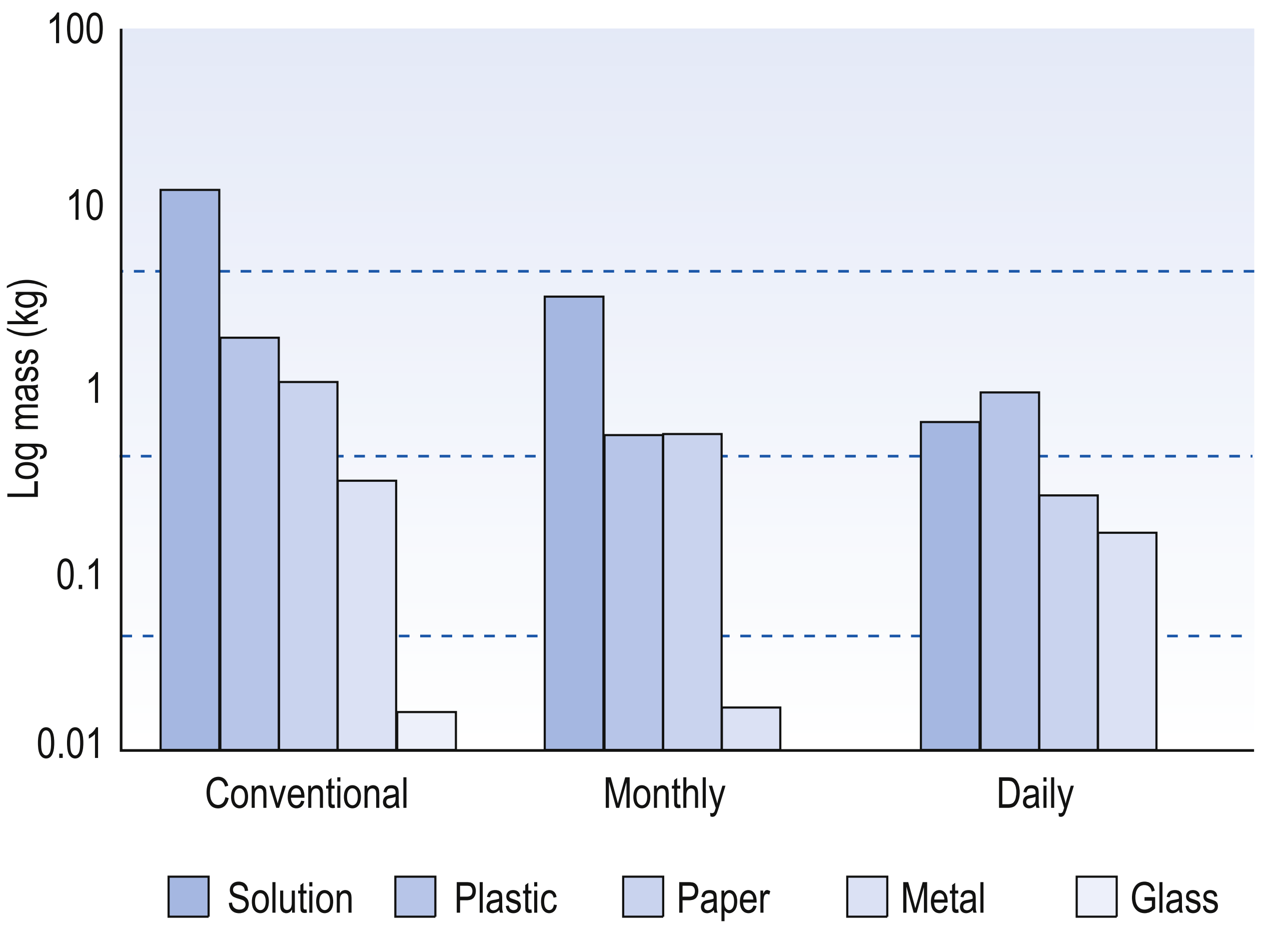

Fig. 18.6 Annual wastage involved in the use of unplanned, monthly and daily replacement systems.

2. Practitioner concerns about patient non-compliance – compliance is always likely to be a problem to some extent. For example, between 10% and 13% of patients reuse daily disposable lenses (Qureshi et al., 1998; Dumbleton et al., 2013). With all contact lens wear, thorough initial and ongoing patient education to promote compliance is essential.
3. Practitioner concerns about non-optical-practice lens supply – the topic of non-optical practice supply is considered in Chapter 19 as part of a discussion of practice management issues.
4. Patient concerns about the cost of full-time wear – daily disposable lenses are the preferred choice for part-time wear, where the cost is lower. As noted above, the distribution of daily disposable lens wear is bimodal, with peaks at 2 days and 7 days per week of wear. Clearly many patients value the convenience over cost in full-time wear.

Corneal Infiltrative Events and Keratitis

The occurrence of corneal infiltrative events (CIEs) is generally considered the key outcome variable in studies of the safety of contact lens wear. Early reports following the release of daily disposable lenses onto the market seemed to indicate a higher risk of developing CIEs with this lens type, compared with reusable lenses (Dart et al., 2008). Those early results are in stark contrast to contemporary studies that demonstrate a 12.5× lower risk of developing CIEs with daily disposable lenses versus reusable lenses (Chalmers et al., 2012).

There are a number of possible reasons for the apparently spurious early results, which failed to demonstrate increased safety with daily disposable lenses. First, when any new product enters the market, and widespread safety and efficacy in the 'real world' is yet to be established, the 'early adopters' tend to be those willing to take risks – a trait that may in turn be consistent with non-compliant behaviour (e.g. reusing lenses). Second, early-generation daily disposable lenses were perhaps perceived by practitioners as a 'problem-solving' tool, resulting in a disproportionate number of patients with pre-existing ocular problems (e.g. papillary conjunctivitis, contact-lens-associated dry eye, excessive corneal and conjunctival staining, etc.) being fitted with these lenses. Thus, the early studies examining safety with daily disposable lenses (Dart et al., 2008) may have reflected lens performance in risk-takers and patients with pre-existing adverse ocular conditions.

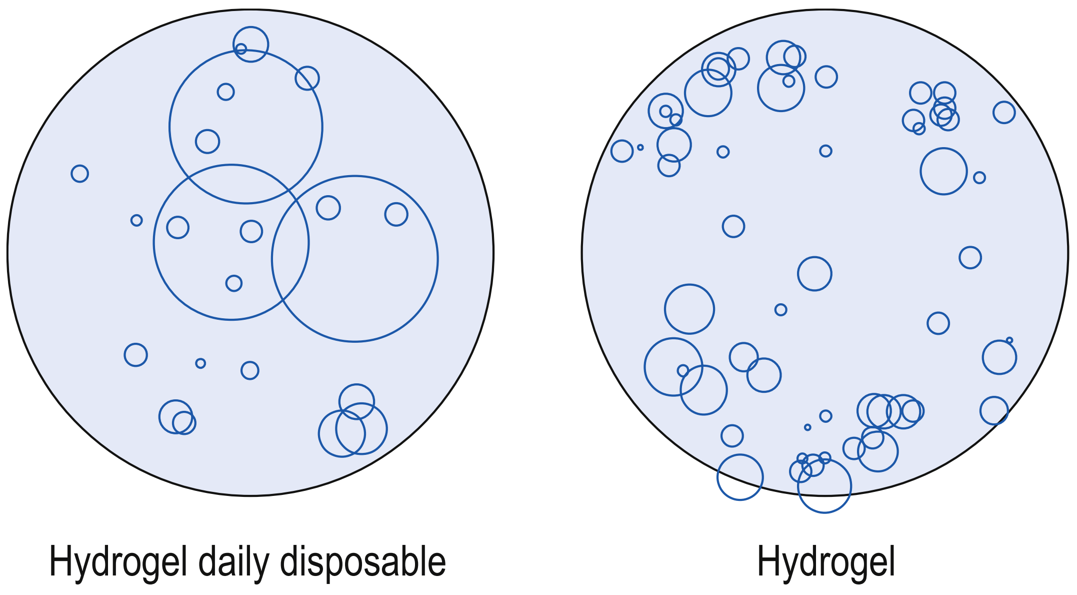

Fig. 18.7 Distribution and size of corneal infiltrative events (blue circles) in patients wearing daily disposable hydrogel lenses versus all other forms of daily hydrogel lens wear. The two large black circles represent corneas (right eye representation).

Numerous other studies have confirmed a lower rate of CIEs with daily disposable lenses compared with reusable lenses. Lazon de la Jara et al. (2013) reported a lower incidence of CIEs with Senofilcon A contact lenses (Johnson & Johnson Vision Care, Jacksonville, FL) used on a daily disposable basis, compare with compliant reuse of the same lenses with either hydrogen peroxide or multipurpose disinfection solutions. These authors also noted that comfort at insertion was significantly worse for participants who experienced CIEs than for those who did not.

Chalmers et al. (2015) reported annual rates of occurrence of CIEs of 0.4% and 0% in patients wearing silicone hydrogel versus hydrogel daily disposable lenses, respectively. These rates were significantly lower than annual CIE rates reported with reusable soft lenses (3–4%), indicating improved safety outcomes with daily disposable lenses.

Efron et al. (2005) examined the distribution of CIEs of all levels of severity in symptomatic contact lens wearers presenting to a hospital emergency clinic. Fig. 18.7 shows the distribution of CIEs in patients wearing daily disposable hydrogel lenses versus all other forms of daily hydrogel lens wear; CIEs tended to occur more towards the lens periphery in those wearing reusable hydrogel lenses and more towards the lens centre in those wearing daily disposable hydrogel lenses.

Efron et al. (2005) suggested that the disproportionately greater number of corneal infiltrates occurring in the periphery of those using reusable hydrogel lenses is related to the typical methods adopted by patients for manually cleaning soft lenses. The two classic techniques used to clean contact lenses with solutions are: (1) to place the lens on the palm of one hand and rub the lens in a circular motion with the index finger of the other hand, and (2) to rub the lens between the index finger and thumb (Stein et al., 2002). In both cases, there is a tendency for the cleaning effect to be concentrated towards the centre of the lens, which leads to a higher concentration of deposits, such as denatured proteins, in the lens periphery compared with the more thoroughly cleaned lens centre (Heiler et al., 1991). Lens deposits can compromise corneal integrity in a number of ways, such as: having a direct mechanical effect, harbouring environmental antigens and causing an immunological reaction in the adjacent cornea, or harbouring microorganisms and inducing an infection in the underlying cornea. Excess deposits in the lens periphery resulting in these forms of compromise in the peripheral cornea could account for the distribution of infiltrates observed in patients wearing reusable hydrogel lenses in this study.

Given the above arguments, it would be expected that daily disposable lenses – which are discarded after each use and never manually cleaned – would be associated with a random distribution of infiltrates. However, a disproportionately greater number of infiltrates were observed towards the centre of the corneas of patients wearing such lenses. Efron et al. (2005) suggested that this may relate to patterns of lens contamination from the fingers of patients at the time of lens insertion. That is, prior to lens insertion, patients typically 'fish' the lens from the blister pack with the forefinger, which is placed on or near the centre of the lens as it is removed. Thus, there is a greater propensity for contamination of the centre of the lens, and for such contaminants to be transferred directly to the centre of the cornea upon lens insertion, inducing infiltrates in that location.

Radford et al. (2009) reported that, compared with planned-replacement soft lenses, daily disposable lenses significantly reduced the risk of toxic/hypersensitivity and metabolic disorders.

There are reports of Acanthamoeba keratitis in patients who reuse daily disposable contact lenses. Diagnosis can be difficult to make, but should still be considered in all patients who wear contact lenses, including daily disposable lenses (Niyadurupola and Illingworth, 2006). Full compliance, however, cannot necessarily eliminate the risk of microbial keratitis; cases of Pseudomonas keratitis have been reported in fully compliant occasional users of daily disposable lenses (Munneke et al., 2006; Batta and Goldstein, 2010). In these cases, lenses were not overworn, reused or slept in – all risk factors for corneal infection.

Two studies have determined the incidence of microbial keratitis with daily disposable lenses. Morgan et al. (2005) reported an incidence of 4.9 and 6.4 cases of severe (microbial) keratitis per 10 000 wearers per year with daily disposable hydrogel lenses and 'other' hydrogel lenses, respectively. Stapleton et al. (2008) reported an incidence of 2.0 and 1.9 cases of microbial keratitis per 10 000 wearers per year with daily disposable hydrogel lenses and 'other' hydrogel lenses, respectively. However, in patients who occasionally slept overnight in daily disposable hydrogel lenses, the incidence of microbial keratitis increased to 4.2 cases per 10 000 wearers per year.

The above reports suggest that, for daily lens wear, daily disposability does not appreciably reduce the risk of severe microbial keratitis compared with planned lens replacement protocols. However, Carnt and Stapleton (2016) suggest that Acanthamoeba keratitis can be avoided by fitting patients with daily disposable lenses, as this will likely minimize contact with water, which is a primary risk factor.

Lens Application to Assist Ametropes in Eyewear Selection

In a practice setting, daily disposable lenses can be offered to ametropic non-lens wearers prior to spectacle dispensing so they can clearly visualize their appearance at a comfortable distance from the mirror with different styles of spectacle frames. Atkins et al. (2009) adopted this strategy in a clinical trial and found that the opportunity to try contact lenses prior to spectacle dispensing was well received by patients who generally reported a very positive experience. In particular, contact lenses assisted in seeing frame detail and suitability for wear. One-third of subjects proceeded to purchase contact lenses. Atkins et al. (2009) recommended that practitioners consider offering daily disposable contact lenses to all suitable patients who are proceeding to spectacle dispensing to optimize the dispensing process and to provide an opportunity to try contact lenses.

Conclusion

It is likely that all lenses prescribed in the future will be 'single-use' products, such as daily disposable or extended-wear lenses. However, patients who wear daily disposable contact lenses should be reminded that the benefits of this modality of contact lens are possible only if the lenses are worn once and thrown away, and not worn overnight.

Access the complete references list online at http://www.expertconsult.com.

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19

Reusable Soft Lenses

JOE TANNER | NATHAN EFRON

Introduction

In this book, the term 'reusable lenses' refers to lenses that are removed from the eye, cleaned and stored in a lens case for a period of time (typically overnight), and then reapplied to the eye the following day (or at a later date if lenses are not worn for a while).

Disposable lenses, which were designed to be reused for a length of time between 1 week and 1 month, were released internationally in the late 1980s (Fig. 19.1). Prior to this, the same reusable lenses were worn for many months or years, until they were damaged or deemed to be unwearable. The acceptance of disposability by practitioners and patients has been one of the most significant changes in the contact lens market. In a survey of six nations in 2001 (Australia, Canada, Greece, Netherlands, Norway and the UK), over 90% of soft lenses were replaced monthly or more frequently in five out of six nations surveyed (i.e. Australia, Canada, Netherlands, Norway and the UK, but not Greece) (Morgan et al., 2002).

Fig. 19.2 shows trends in the extent of prescribing reusable lenses in Australia between 2000 and 2015. It can be seen that the prescribing of lenses intended to be replaced at periods greater than 1 month fell from 17% of all new soft lens fits in 2000 to 0% in 2015. Over the same period, lenses designed for 1- to 2-weekly replacement has also dropped away to 1%, meaning that virtually all soft lenses prescribed in Australia in 2015 were for either monthly or daily replacement. Similar trends have been documented in many international markets (Morgan et al., 2016).

The Acuvue lens (Johnson & Johnson) was initially packaged in plastic boxes, but this was soon replaced by cardboard boxes for reasons of reduced cost and packaging efficiency (to enable storage of the maximum number of lenses per unit volume). The NewVues lens (CIBA Vision) was originally supplied in glass vials, but this was soon changed to blister packs for the same reasons. The form of packaging initially used for the SeeQuence lens (Bausch & Lomb) is now adopted by virtually all disposable lens manufacturers. Products replaced at least monthly have invariably been designed, packaged and promoted for replacement at specific intervals. However, this applies less for lenses replaced 3-monthly, and is almost never the case for lenses offered for biannual and annual replacement; such lenses are usually conventional lenses packaged in vials (Fig. 19.3), and many of these lenses were developed prior to widespread use of planned replacement. Lenses designed to be replaced at intervals of more than 1 month are rarely prescribed today.

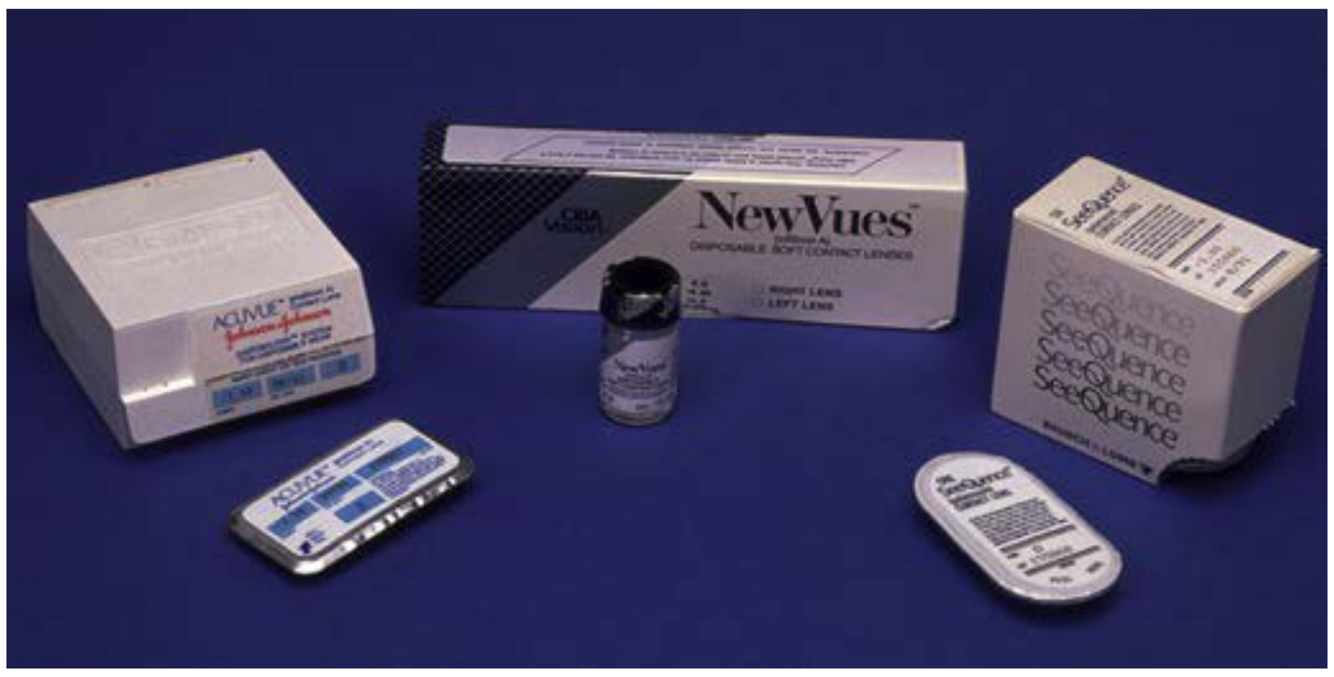


Fig. 19.1 The first disposable lenses released on to the international market in the late 1980s. Left: The Acuvue lens (Johnson & Johnson Vision Care). Centre: NewVues lens (CIBA Vision). Right: SeeQuence lens (Bausch & Lomb).

Planned lens replacement has been shown to be clinically useful for extended-wear applications, and since their advent in 1998 silicone hydrogel soft lenses for both extended and daily wear have been marketed on a planned replacement basis. Discussion of planned lens replacement in this chapter will be confined to lenses intended to be used on a daily-wear basis (i.e. lenses that are not worn overnight) for at least a week. The specific issue of planned replacement of extended-wear lenses is dealt with in Chapter 24 and daily disposable lenses are specifically covered in Chapter 18.

Advantages of Planned Replacement

Long-term adverse changes in contact lenses when lenses are not replaced on a planned basis were learned from bitter experience in the early days of soft lenses, prior to the introduction of frequent replacement lenses in the late 1980s.

Soft contact lenses have a reactive surface and a low modulus of elasticity, rendering them more susceptible to damage. Furthermore, any damage to the surface or edge of the lens cannot be repaired because a hydrated soft lens cannot be repolished. Although these factors would seem to indicate the desirability of regular soft lens replacement, the high cost of soft lenses throughout the 1970s and much of the 1980s precluded such, so strategies were devised to prolong lens life for as long as possible. The norm during this period was to prescribe soft lenses in the same way that rigid lenses were being prescribed – that is, for the patient to keep using the same pair of lenses until they became damaged or lost, were too uncomfortable to wear, resulted in a noticeable deterioration of vision or induced ocular pathology that was either self-diagnosed or detected during an eye examination. Some patients were known to use the same pair of lenses for up to 7 years. Indeed, it was even possible to take out insurance policies against the risk of lens loss or damage.

All of this changed with the introduction of planned lens replacement schemes and disposable lenses in the late 1980s. This concept rapidly became established and it is now universally accepted that contact lenses must be replaced regularly. In fact, a recent survey of international prescribing trends conducted by Morgan et al. (2016) revealed that, across 34 countries,

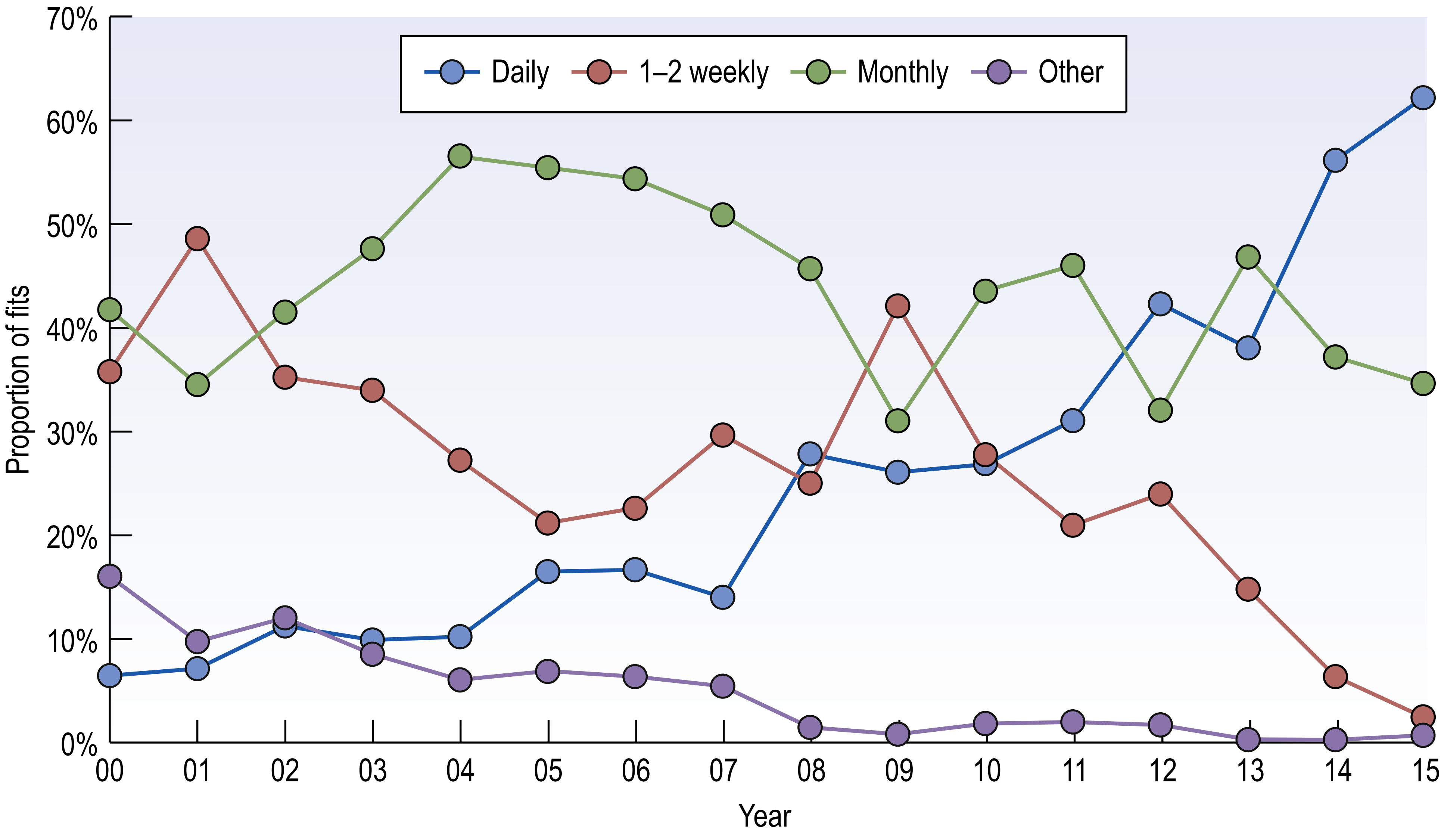


Fig. 19.2 Percentage of soft lens new fits prescribed according to replacement frequency in Australia between 2000 and 2015.

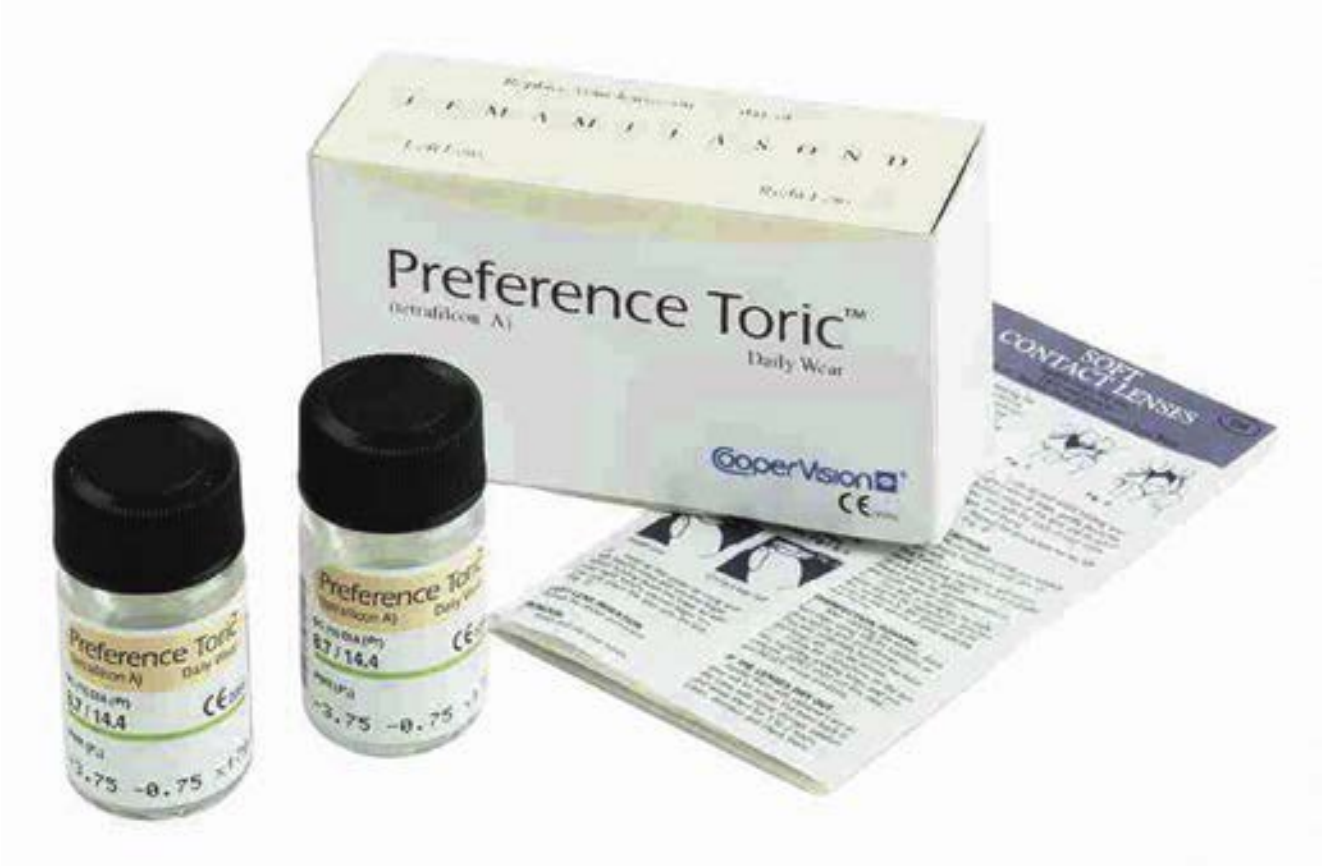


Fig. 19.3 Example of a non-disposable planned replacement lens. This lens is replaced 3-monthly.

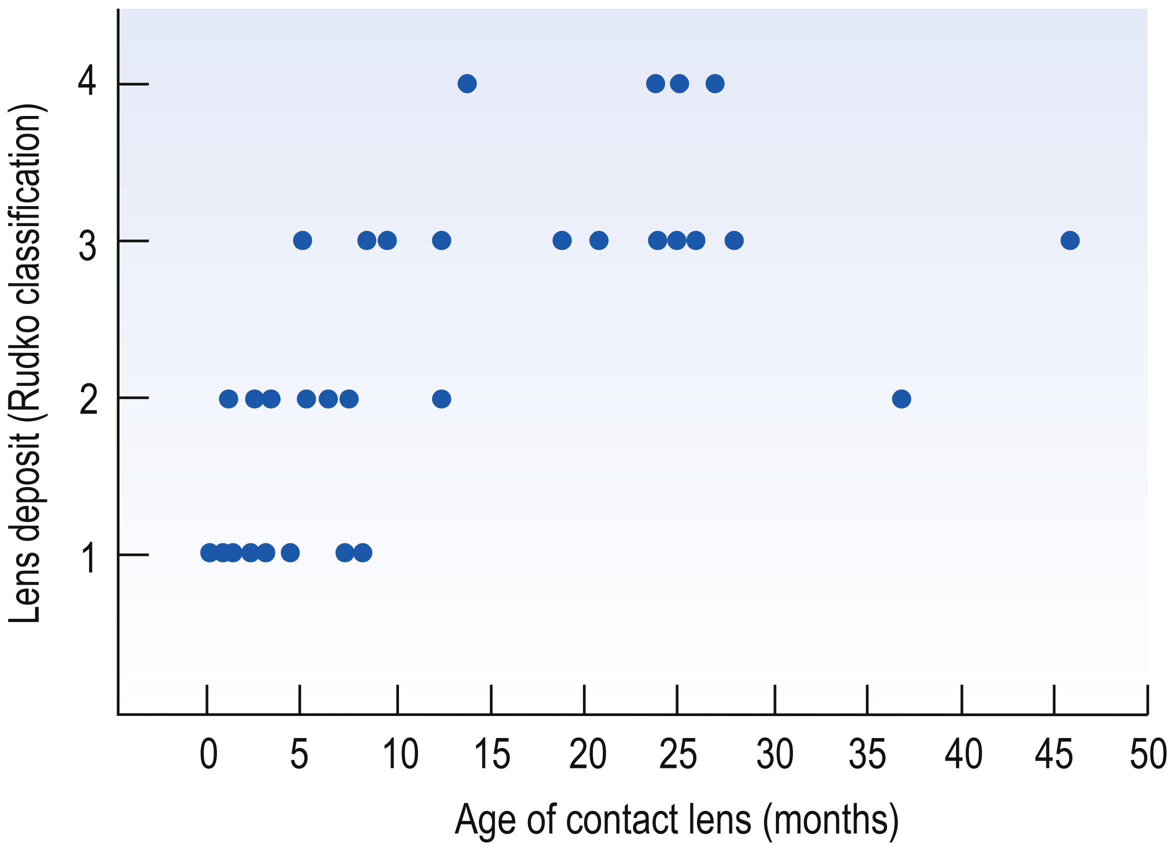


Fig. 19.4 Relation between lens deposition (determined using the Rudko classification system) on non-replacement hydroxyethyl methacrylate (HEMA) lenses versus lens age (months). (Adapted from Gellatly, K. W., Brennan, N. A. & Efron, N. (1988). Visual decrement with deposit accumulation on HEMA contact lenses. Am. J. Optom. Physiol. Opt., 65, 937–941.)

unplanned replacement represented only 1% of all soft contact lens fits, and was 0% in 28 countries.

The rationale for the planned replacement of soft contact lenses is simple: cleaner lenses should produce fewer adverse ocular effects. A significant proportion of clinical problems relating to the wear of soft contact lenses can be attributed to deposition on the lens surface with tear-derived substances. Contact lens deposits result in reduced acuity, comfort and wettability and increased inflammatory complications such as papillary conjunctivitis and acute red eye (Jones et al., 2000). All soft contact lenses suffer gradual spoilation from the environment and tear film components over time. Daily cleaning and periodic protein removal can slow this rate of deposition but not prevent its occurrence.

AVOIDANCE OF LONG-TERM ADVERSE CHANGES IN CONTACT LENSES

There are currently no indications for non-planned replacement of soft lenses. This raises the question of why a virtually obsolete, non-indicated practice should even be considered in a 21st-century contact lens textbook. Perhaps more than anything else, this section will serve as a reminder of the reason why it is considered necessary to replace lenses on a regular basis.

Lens deterioration over time manifests in a variety of ways and is attributable to many factors. Lenses become deposited, irreversibly lose water, suffer surface damage and can become contaminated during storage. Each of these factors will be considered in turn.

Lens Deposits

The extent of lens deposition increases over time (Fig. 19.4) (Gellatly et al., 1988). Numerous factors, many of which are interactive, are involved in the formation of deposits on the front or back surface of contact lenses. These factors include lens wear modality (daily or continuous wear), the bulk chemical composition of the lens, lens water content, the physicochemical nature of the lens surface (such as ionicity), the chemical

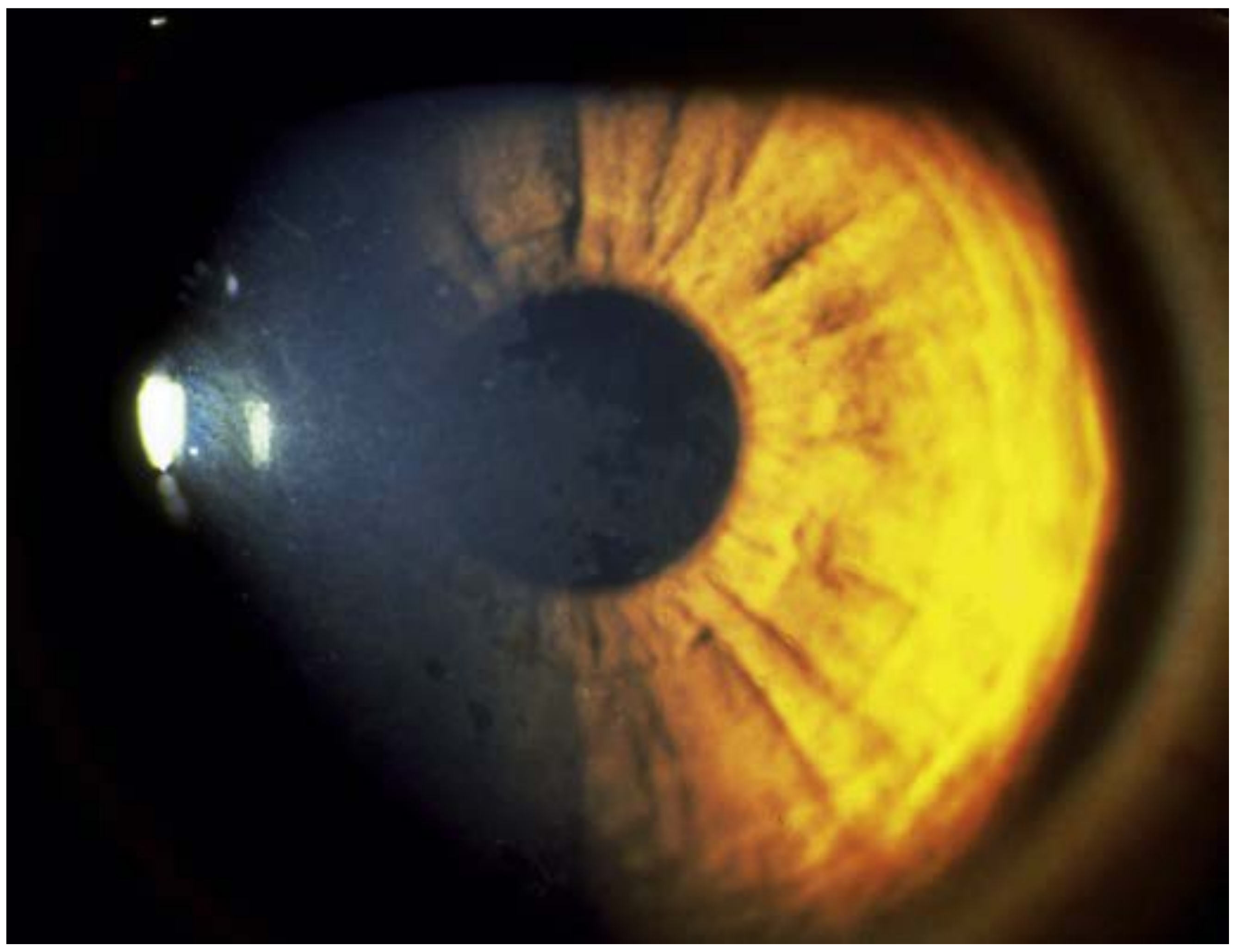


Fig. 19.5 Film of protein on a soft lens worn on a non-replacement basis. (Courtesy of Patrick Caroline, Bausch & Lomb Slide Library.)

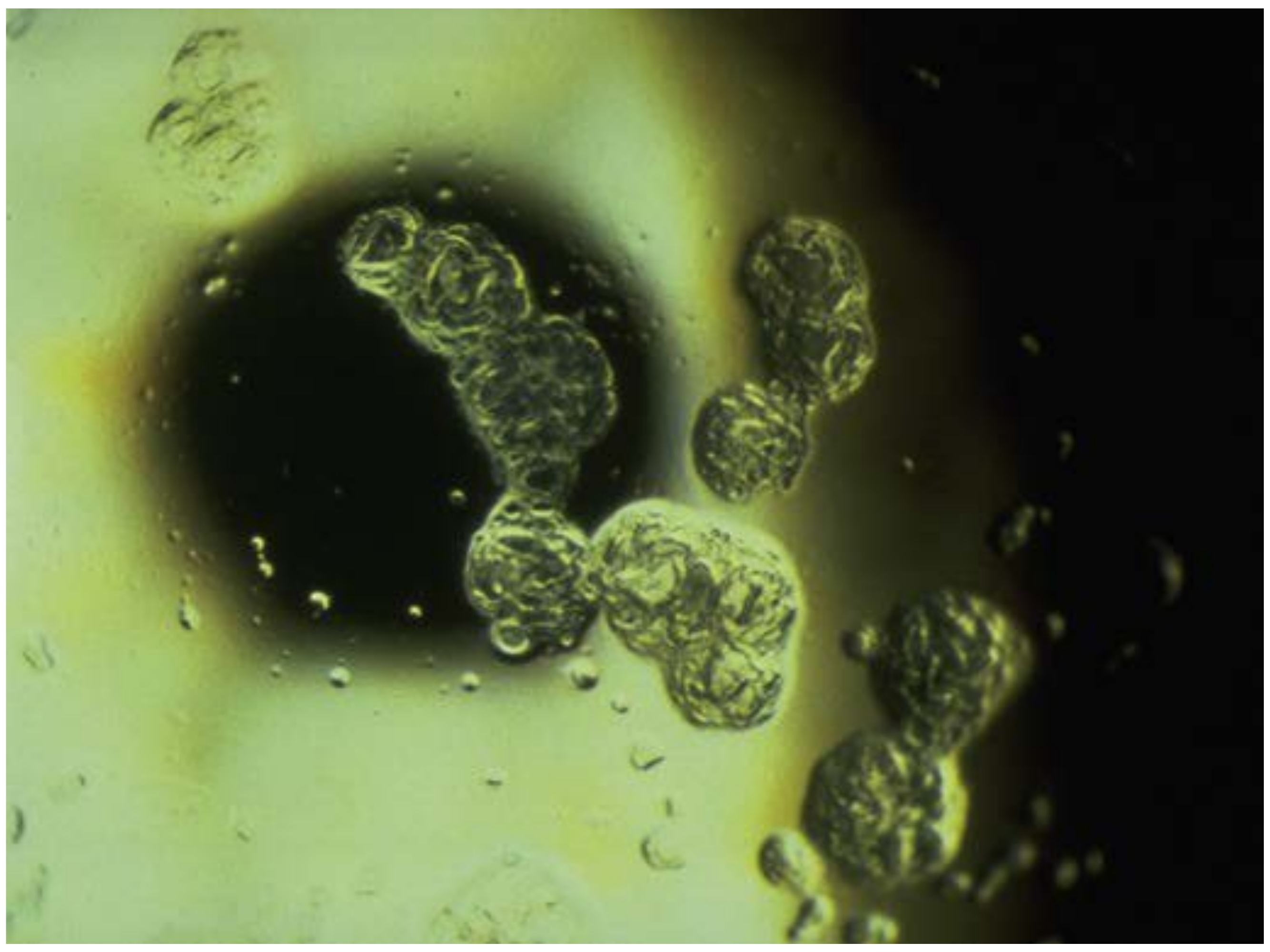


Fig. 19.6 'Jelly bumps' on a soft lens worn on a non-replacement basis. (Courtesy of Patrick Caroline, Bausch & Lomb Slide Library.)

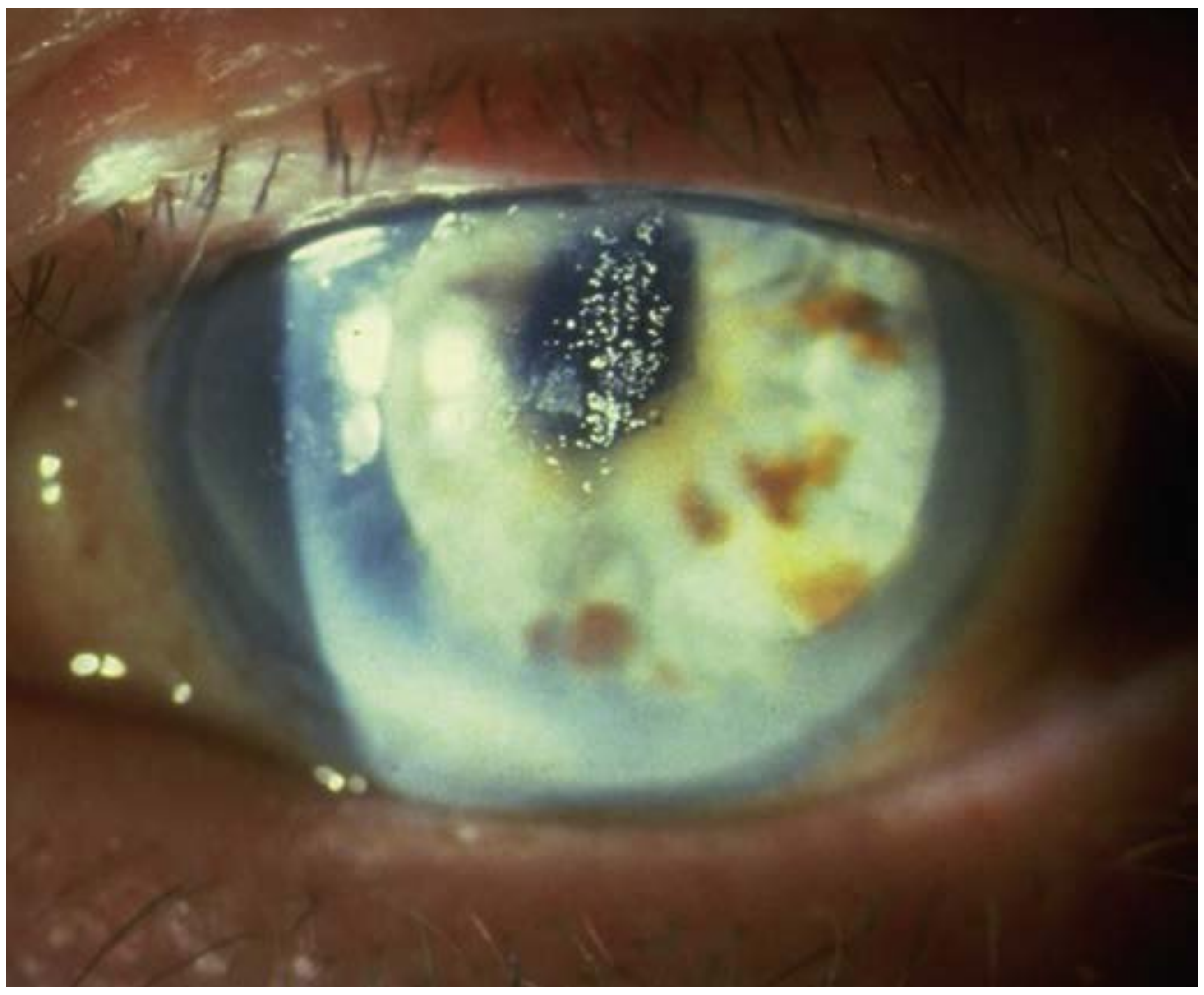


Fig. 19.7 Calcium deposits on a soft lens worn on a non-replacement basis. (Courtesy of Bausch & Lomb Slide Library.)

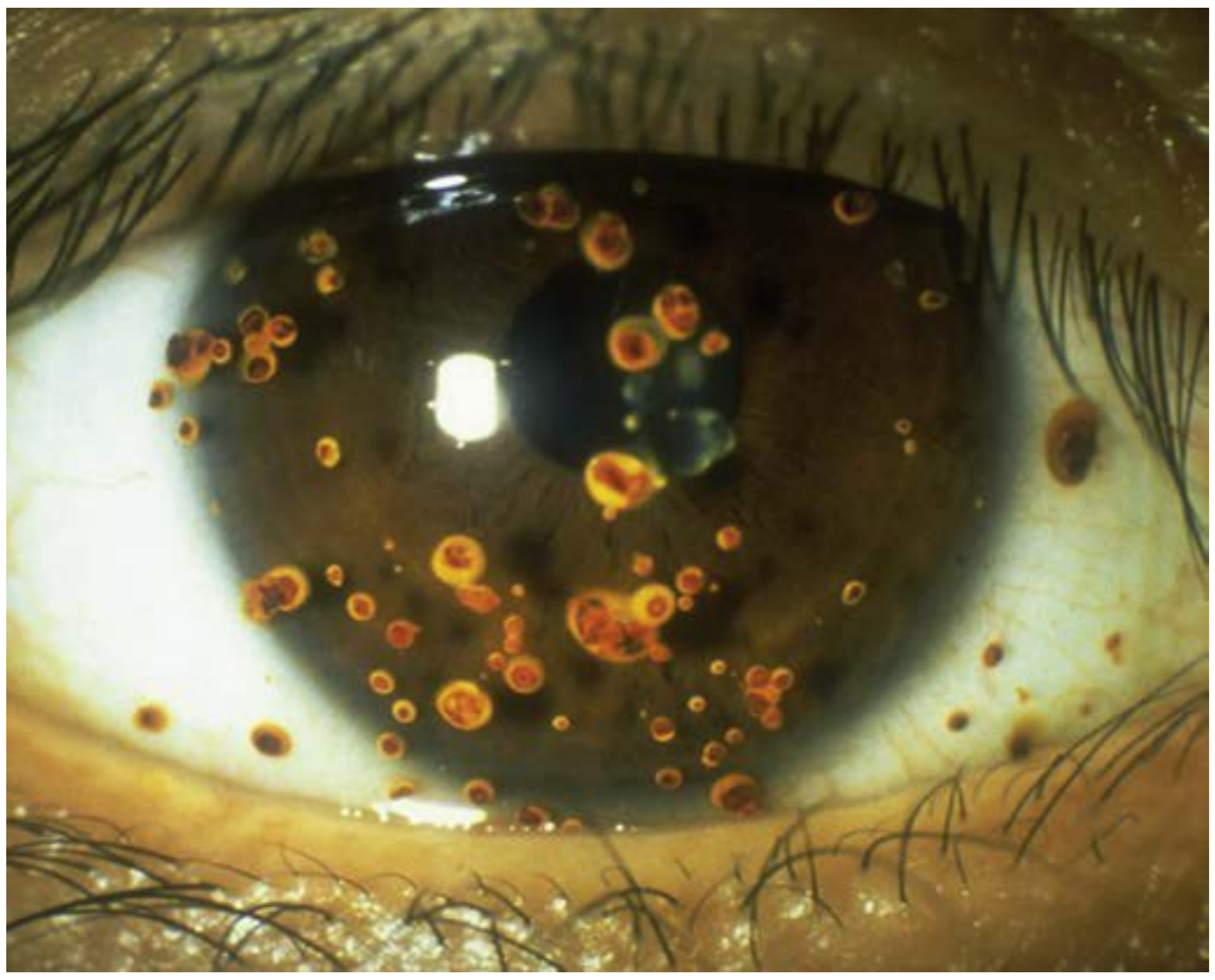


Fig. 19.8 Iron deposits on a soft lens worn on a non-replacement basis. (Courtesy of Patrick Caroline, Bausch & Lomb Slide Library.)

composition of lens maintenance solutions, the adequacy of lens maintenance procedures (a measure of patient compliance), hand contamination, proximity to environmental pollutants and intrinsic properties of the patient's tears (Tighe et al., 1991; Maissa et al., 1998). The most common tear-derived components of lens deposits are proteins (Jones et al., 1997), which cannot be detected under normal conditions. A heavy deposition of protein can manifest as a general haze on the lens surface (Fig. 19.5) and extensive lipid formation can appear as a clear smear or smudge on the lens surface.

Visible soft lens deposits take months or years to form, and are thus encountered only in patients wearing lenses on a non-planned replacement basis. The most common form of visible deposition that is derived from the tear film is known as 'jelly bumps' or 'mulberry deposits' (Fig. 19.6), which consist of various layered combinations of mucus, lipid, protein and sometimes calcium. Barnacle-like calcium carbonate deposits (Fig. 19.7), which are also derived from the tear film, can project anteriorly and be a source of discomfort. Iron deposits (Fig. 19.8), which contaminate the lens from exogenous sources, appear as small red-orange spots or rings and form when iron particles become embedded in the lens and oxidize to form ferrous salts. These were often seen in patients who frequently commute on trains or trams, as there is a high probability of fine iron particles – which are thrown into the air as the vehicle moves along the steel tracks – coming to rest on the lens surface.

It is clear that proteins and lipids from the tears can deposit on soft lenses within minutes of insertion (Jones et al., 1997); however, such deposits are thought to be innocuous over periods of less than 1 month. Lipid is easily removed with surfactant cleaning. A small amount of protein deposition may even be beneficial to the eye, as long as it does not become denatured, because the protein forms a natural biocompatible lens coating (Sack et al., 1987; Omali et al., 2015). Although these rapidly forming deposits cannot be seen and do not generally compromise vision or comfort, they can reduce lens surface wettability (Jones et al., 1996a).

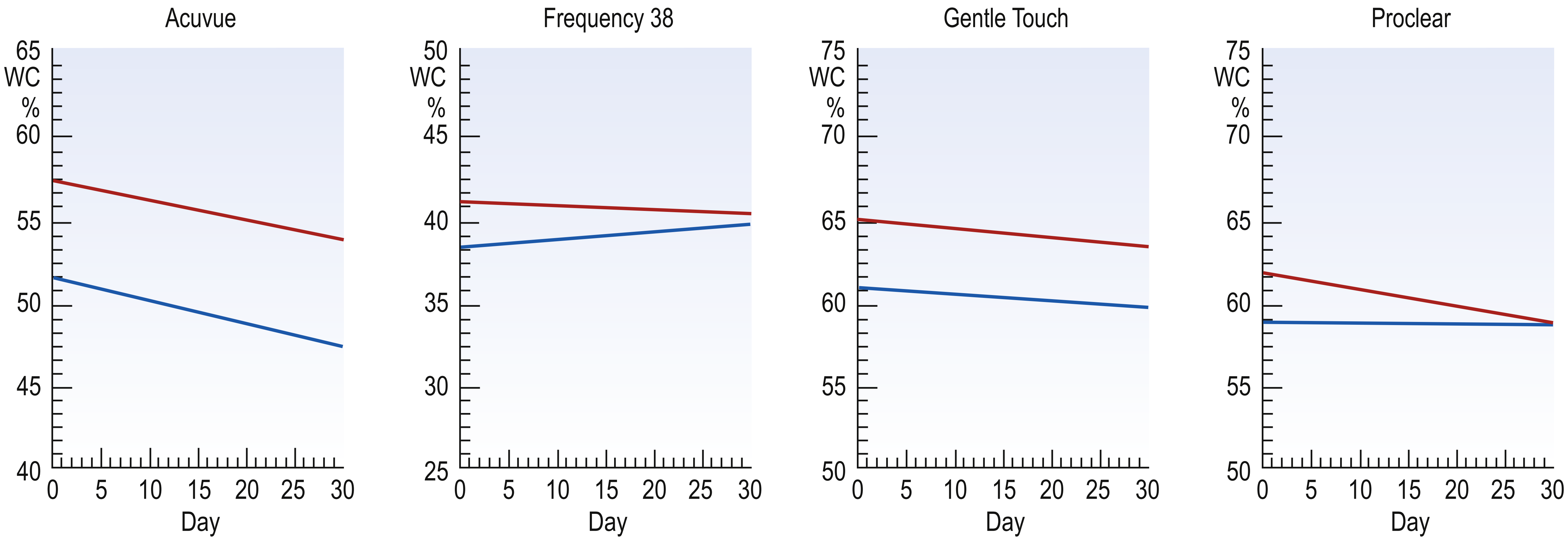


Fig. 19.9 Relation between pre-insertion water content (WC: red regression line) and post-removal water content (blue regression line) versus time for the Acuvue, Frequency 38, Gentle Touch and Proclear lenses. The ageing effect is indicated by the decrease in pre-insertion water content over time. (Adapted from Morgan, P. B. & Efron, N. (2000). Hydrogel contact lens ageing. CLAO J., 26, 85–90.)

Long-term protein deposition can be problematic because, in time, it can become denatured and thus no longer 'recognized' by the eye, leading to an adverse immunological reaction (Sack et al., 1987). Lens surface protein can also absorb, and concentrate, preservatives and other active ingredients in contact lens care solutions, which may be released back into the eye in noxious concentrations, leading to toxic reactions. The physical presence of excess deposits can also cause direct mechanical insult to the anterior eye.

Soft lenses can also become discoloured over extended time periods (many months or years). The cause may be intrinsic or extrinsic. High levels of melanin can lead to a brown discoloration. Nicotine can become absorbed into the lenses of patients who smoke or spend time in a smoky environment, leading to an orange-brown discoloration. Exposure to mercury can lead to a black / grey discoloration. Extreme lens discoloration can be cosmetically unsightly to an onlooker.

Irreversible Water Loss

Morgan and Efron (2000) noted a significant lens ageing effect whereby the pre-insertion lens water content decreased significantly over a 28-day cycle for four soft lens types evaluated (Fig. 19.9). This ageing process is different from the well-known phenomenon of lens dehydration over the course of a number of hours throughout a day. Although this irreversible water loss was monitored for only 28 days, the trend clearly indicated that water loss would continue well beyond this timeframe, albeit at a progressively slower rate.

It is clear that a combination of physical and / or physiological factors caused a reduction in water content of the hydrogel lenses examined by Morgan and Efron (2000). It follows that some change to the lens appears to have caused a progressive reduction in water uptake by the lens each night during storage, in what amounts to a 'lens-ageing' effect. The most likely explanation for this ageing effect is that lens spoilation acts either to displace water from the lens or to alter the nature of the lens material in such a way that less water is absorbed by the lens. Some significant intersubject differences in lens dehydration were observed; the range of daily dehydration for the group of six subjects investigated by Morgan and Efron (2000) was 1.7–5.9% for all lenses for all days. These differences may relate to intersubject differences in ocular physiology.

One of the most important clinical ramifications of this phenomenon is that there is an associated loss of oxygen performance with dehydration of hydrogel lenses (Efron and Morgan, 1999). Thus, the corneas of patients wearing hydrogel lenses on a non-replacement basis will be more prone to hypoxic complications over time.

Surface Damage and Crazing

All soft lenses are manufactured with a shelf-life, which primarily indicates how long the lens can be guaranteed to be sterile. In addition, there is the possibility of natural polymer degradation over time, whereby clinically relevant changes could be noticed after about 5 years from the time of manufacture.

It is self-evident that physical trauma can lead to a variety of lens defects. If a defect is obvious – such as a large piece of the lens breaking off – then the patient will typically notice this and discard the lens. If such a defect is not noticed, discomfort on insertion will normally alert the wearer to this problem. However, small defects may not be noticed, which is potentially problematic because such defects can compromise ocular integrity at a subclinical level (Efron and Veys, 1992).

Storage Contamination

For a variety of reasons, patients may suspend lens wear for extended periods of time, for reasons such as not wearing lenses when unwell or when travelling. Also, for a variety of lifestyle reasons, some patients wear lenses only very occasionally. The potential for contamination of the lens and storage case during such periods is potentially problematic (Szczotka-Flynn et al., 2010). In particular, some contact lens storage solutions are inefficacious at killing fungi, which have a propensity for invading the lens matrix and destroying lenses in storage (Fig. 19.10) (Wilson and Ahearn, 1986). Stringent measures need to be enforced for the preservation of lenses during long-term storage, such as regular cleaning and disinfection and the use of storage solutions known to be highly efficacious at killing all forms of microorganisms.

AVOIDANCE OF LONG-TERM ADVERSE CHANGES IN THE ANTERIOR EYE

By ensuring that soft lenses are replaced at a suitable predetermined interval, one of the most enduring medical management axioms – that of prevention being better than cure – is brought

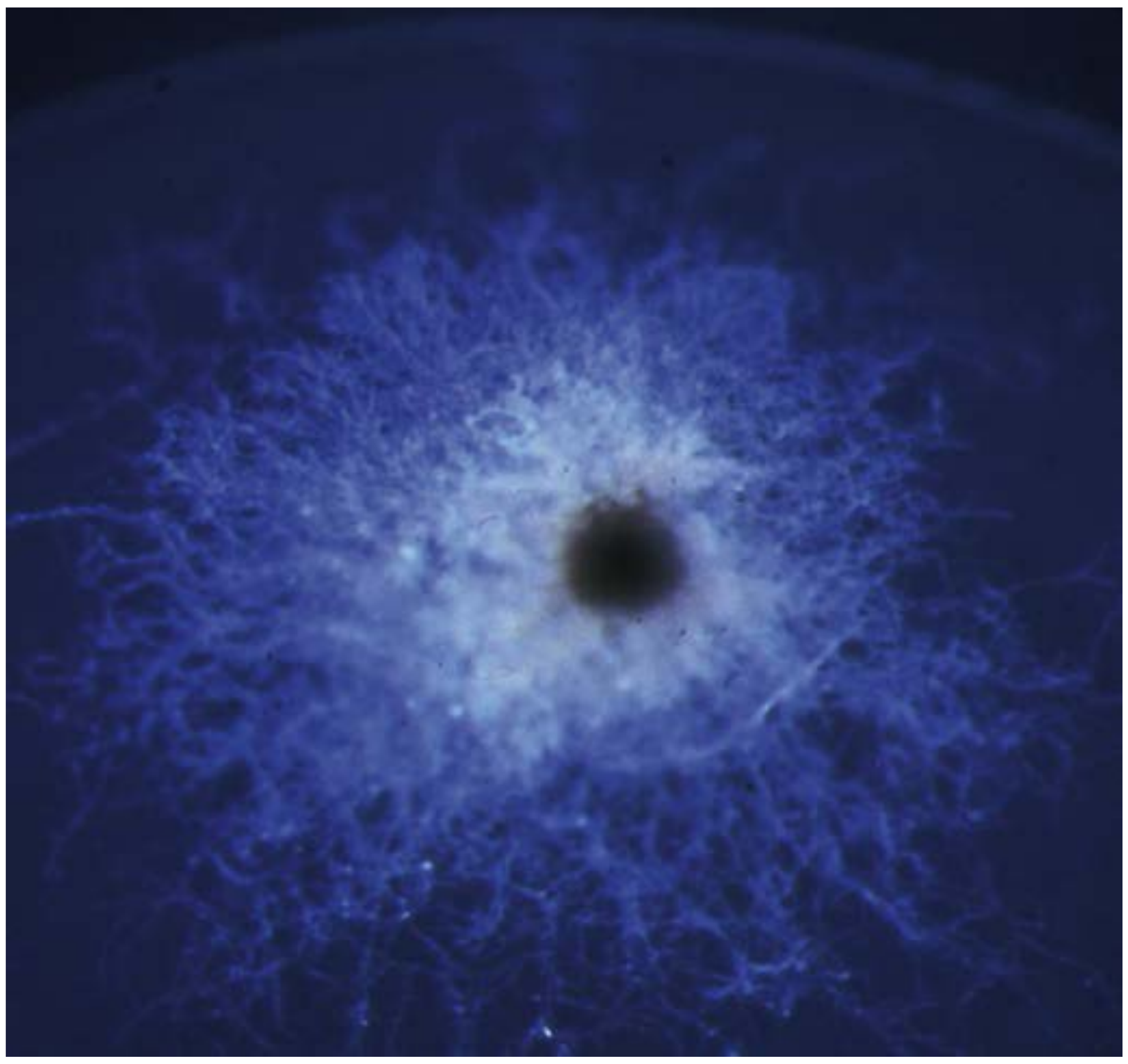


Fig. 19.10 Fungal growth within the matrix of a non-replacement soft lens following long-term storage in a solution of low antifungal efficacy. (Courtesy of Nicola Pritchard, Bausch & Lomb Image Library.)

to bear. In practice, patients who replace lenses regularly report fewer symptoms and exhibit fewer physiological changes in most instances (Marshall et al., 1992; Poggio and Abelson, 1993; Nilsson and Montan, 1994; Pritchard et al., 1996; Nilsson, 1997; Porazinski and Donshik, 1999; Chalmers et al., 2012), compared with patients who do not replace lenses regularly.

Primary indicators of long-term lens degradation include symptoms of discomfort and reduced vision, and signs associated with adverse ocular reactions.

Discomfort

As indicated above, numerous factors can lead to lenses becoming less comfortable over time; these include the existence of microscopic lens defects, physical trauma and/or immunological reaction due to lens deposition, and progressive hypoxic effects due to lens ageing. In a retrospective study of nearly 2000 2-weekly and non-planned replacement daily-wear patients, Poggio and Abelson (1993) found a higher rate of symptoms in the non-planned replacement group.

Brennan and Efron (1989) surveyed the symptoms experienced by 104 patients wearing hydroxyethyl methacrylate (HEMA) lenses that were not being replaced on a planned basis. They found a clear and statistically significant association between the symptom of dryness and age of the lenses. Of those patients whose lenses were older than 6 months, 31% often experienced dryness, whereas only 12% of patients whose lenses were less than 6 months old experienced this symptom (Fig. 19.11).

Reduced Vision

The loss of vision associated with deposit accumulation on HEMA contact lenses was assessed by Gellatly et al. (1988) in 51 patients presenting consecutively to a large clinic. Both high- and low-contrast visual acuity decreased with increased deposition and with lens age. As a general rule, unacceptable vision loss and deposit formation occurred after 12 months or 4000 hours of lens wear (Fig. 19.12).

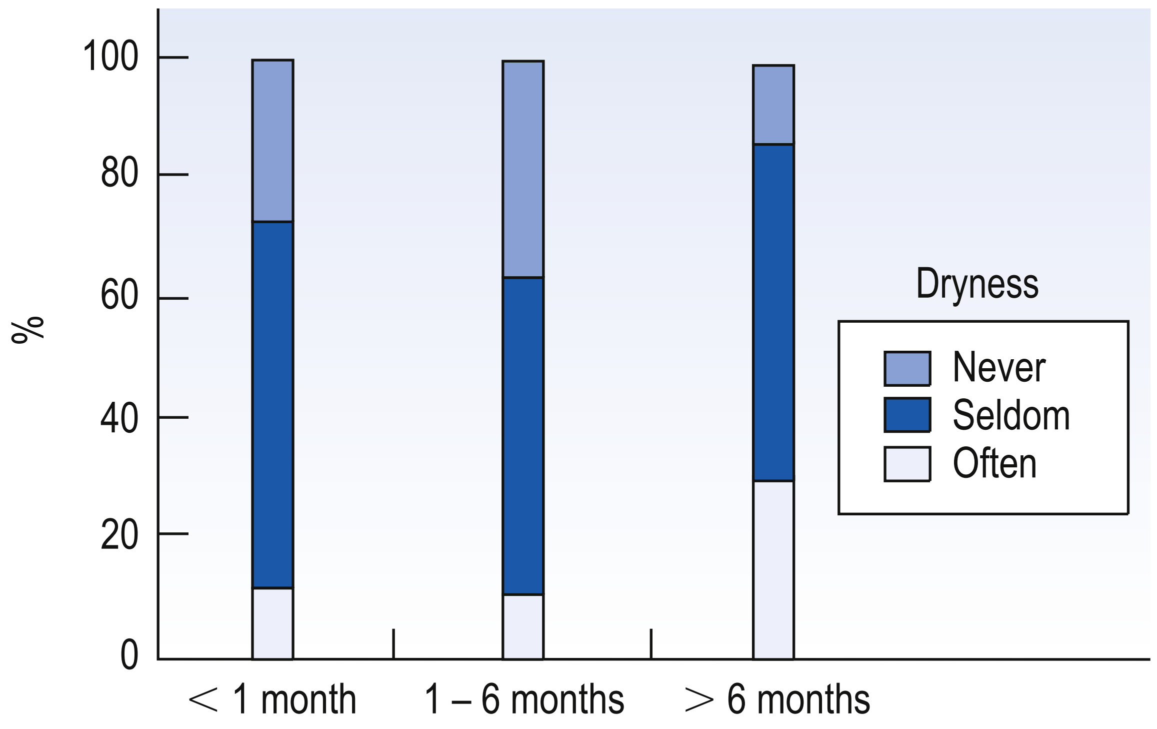


Fig. 19.11 Frequency of the symptom of dryness among users of non-replacement hydroxyethyl methacrylate (HEMA) lenses, categorized by lens age. (Adapted from Brennan, N. A. & Efron, N. (1989). Symptomatology of HEMA contact lens wear. Optom. Vis. Sci. 1989, 66, 834–838.)

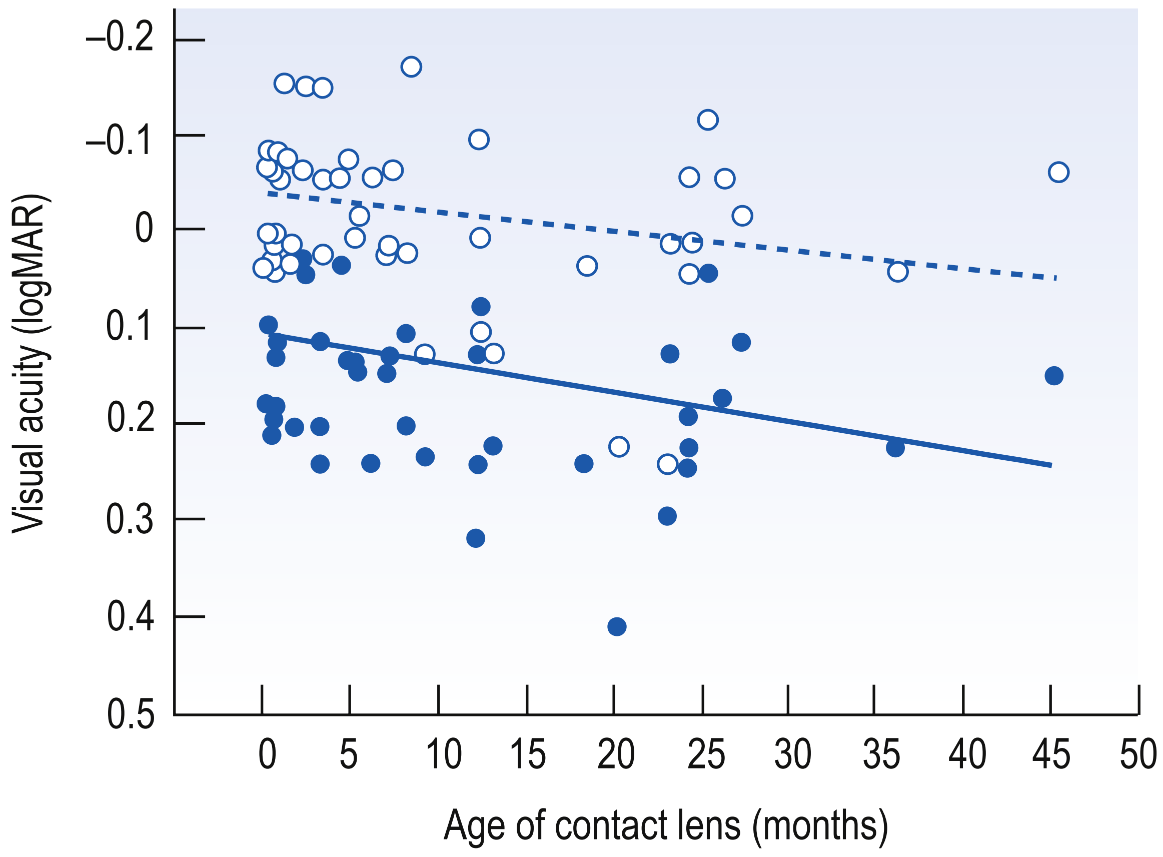


Fig. 19.12 Relation between high-contrast visual acuity (logMAR) (open circles and dotted line) and low-contrast visual acuity (logMAR) (closed circles and continuous line) during wear of non-replacement hydroxyethyl methacrylate (HEMA) lenses versus lens age (months). (Adapted from Gellatly, K. W., Brennan, N. A. & Efron, N. (1988). Visual decrement with deposit accumulation on HEMA contact lenses. Am. J. Optom. Physiol. Opt., 65, 937–941.)

Ocular Surface Pathology

Numerous authors have reported that patients using non-planned lens replacement systems suffer from a higher incidence of adverse ocular reactions compared with patients using planned replacement lenses. Although planned replacement lenses are made of similar materials, and have a similar design, to lenses supplied on a non-planned replacement basis, the minimization of lens surface deposition on frequently replaced lenses has a significant effect on reducing complication rates (Nilsson, 1997).

Pritchard et al. (1996) observed that there was significantly more clinically relevant corneal staining and conjunctival injection, as well as a higher incidence of infiltrates and lens deposits, in patients using lenses on a non-planned replacement basis. Additionally, the overall satisfaction of patients wearing non-planned replacement lenses decreased over time. Poggio and Abelson (1993), in a retrospective study of nearly 2000 2-weekly and conventional daily-wear patients, found a significantly lower prevalence of complications in the planned replacement group for corneal abrasions, oedema and superficial punctate keratitis. Furthermore, patients wearing planned replacement lenses had a lower rate of symptoms.

AIR OPTIX
breathable contact lenses
AQUA
Alcon
a Novartis company
A
BAUSCH + LOMB
ULTRA contact lenses
with MoistureSeal technology
B
Biofinity
Aquaform Comfort Science
6 contact lenses
CooperVision
C
ACUVUE OASYS
BRAND CONTACT LENSES
WITH HYDRACLEAR PLUS
6 Lenses
UV BLOCKING
D

Fig. 19.13 Examples of reusable spherical silicone hydrogel contact lenses: (A) Air Optix (Alcon); (B) Ultra (Bausch & Lomb); (C) Biofinity (CooperVision); (D) Acuvue Oasys (Johnson & Johnson Vision Care).

Soon after their introduction onto the market, disposable lenses were recognized as an effective management strategy for specific complications of lens wear such as contact-lens-associated papillary conjunctivitis, sterile infiltrative keratitis and bulbar hyperaemia (see Chapter 40). Papillary conjunctivitis especially has been shown to decrease with more-frequent lens replacement – typically 1 month or less (Porazinski and Donshik, 1999).

Nilsson and Montan (1994) retrospectively evaluated contact-lens-associated keratitis with stromal involvement and concluded that patients wearing lenses on a 2-weekly disposable basis had a significantly lower incidence of keratitis – about one-third the rate – than patients wearing daily-wear soft lenses on a non-planned replacement basis. Similarly, Marshall et al. (1992) found the complication rate for disposable lens wearers to be about one-third of that for those who wore lenses on a non-planned replacement basis.

Although many disposable hydrogel lenses are made from ionic lens materials that accumulate tear protein rapidly, the protein does not denature significantly prior to replacement (Omali et al., 2015). However, a heavy coating of denatured protein may provide binding opportunities for bacteria. Planned replacement is a proven strategy for minimizing the potential adverse effects relating to these phenomena.

USE OF HIGHER-WATER-CONTENT HYDROGEL MATERIALS

There are two strategies for improving the oxygen transmissibility (Dk/t) of contact lenses made from conventional hydrogel materials: reduce the lens thickness profile and/or increase the lens water content. An analysis of these options by Brennan et al. (1991) demonstrated that, particularly at higher powers, the latter strategy is more effective at improving corneal oxygenation. However, lenses made from higher-water-content materials generally have lower elastic moduli and therefore reduced durability than their lower-water-content counterparts. High-water-content materials, particularly those with an ionic surface chemistry, also attract tear film deposits such as jelly bumps and protein at a faster rate (Jones, 1990).

As a result of the above factors, the life expectancy of lenses made from higher-water-content materials is limited to approximately 6 months on average (Jones et al., 1996b). If a planned replacement system is used, then the issues of durability and especially deposit resistance become less significant. Planned lens replacement therefore provides a rationale for the use of medium- to high-water-content hydrogel materials. However, in many countries the great majority of planned replacement lenses fitted use silicone hydrogel materials.

USE OF SILICONE HYDROGEL MATERIALS

Silicone hydrogel lenses (Fig. 19.13) tend to have lower water content and may accumulate surface deposits of significantly different type and quantity to conventional hydrogels (Jones et al., 2003). Although the amount of protein spoilation on these materials tends to be lower, the proportion that is denatured and therefore potentially a cause of contact lens-associated papillary conjunctivitis may be higher. Lipid deposition tends to be greater with silicone hydrogels (Cheung et al., 2007; Nichols, 2013). Planned replacement is therefore still the appropriate strategy for these materials that in many international markets are used significantly more than hydrogels for this purpose.

SIMPLE LENS CARE REGIMENS

Although the need to clean and disinfect reusable soft lenses is self-evident, a powerful argument for prolonging the life of lenses with elaborate lens care systems emerged in the early days of soft lenses because of their relatively high cost of production.

TABLE 19.1 Functional Contact Lens Care for Daily-wear Soft Lenses used for Different Replacement Intervals

Frequency of Lens Replacement	Daily Cleaning	Rinsing	Disinfecting	Protein Removal
Daily	☐	☐	☐	☐
Weekly	☐	☐	☐	☐
Two-weekly	☐	☐	☐	☐
Monthly	☐	☐	☐	☐
Three-monthly	☐	☐	☐	?
Six-monthly or more	☐	☐	☐	☐

By the start of the 1980s, soft lenses were becoming the preferred option in many countries. To achieve the then lens life norm of at least a year, a minimum of three lens care product types were needed. Daily cleaners were used to remove loose deposits and microorganisms from the lens surface; disinfecting solutions were used to kill any remaining microorganisms; and protein removal tablets were used to reduce the build-up of tear proteins on the lens surface. The ongoing cost of these products was often found to be more than that of the contact lenses themselves.

Reusable soft lenses (excluding daily disposable lenses) still need high standards of lens care to ensure safe wear, but the shorter replacement cycles allow some scope for simplification. It should not be necessary to deproteinize lenses changed at least monthly. In cases where lens surface spoilation is a problem with monthly replacement, shortening the replacement interval to 1–2 weeks or even 1 day is likely to be a superior option – at least in terms of patient convenience and therefore compliance – compared with adding a protein removal step to the care regimen.

Table 19.1 outlines the typical functional steps that need to be carried out in the care of lenses replaced at different intervals.

While mechanical daily cleaning, rinsing and disinfection are still essential in the care of 1- or 2-weekly and monthly replacement lenses, in most cases these functions can be effectively achieved with a single lens care product, namely a multipurpose solution (Franklin, 1997) (see Chapter 11).

Typical lens care systems that are used for different planned replacement intervals are listed in Table 19.2.

As the replacement interval increases, the need for a separate protein removal step becomes more likely, although the inclusion of a sequestering agent in multipurpose solutions has been shown to obviate the need for this (Edwards, 1998).

READY AVAILABILITY OF REPLACEMENT LENSES

Lenses replaced weekly, fortnightly or monthly are normally supplied in packs of three or six. It follows that the loss or damage of a lens should not, in most cases, be an inconvenience to a patient wearing disposable lenses. Practices fitting disposable lenses are also likely to have numerous trial lenses, and even stocks of the more popular parameters, on the premises, which enables rapid replacement if lens loss or damage occurs.

ENHANCED COMPLIANCE WITH AFTERCARE SCHEDULES

Planned replacement protocols require patients to return at regular intervals for fresh lenses. Aftercare visits can be scheduled to coincide with lens collection, which is a further benefit of prescribing this modality. Morgan et al. (2011) observed reduced compliance in lens wearers who have not consulted their eye care practitioner for some time. The behaviours associated with the lowest levels of compliance in that study were rubbing and rinsing, handwashing, correct lens replacement and case cleaning.

TABLE 19.2 Typical Lens Care Systems for Daily-wear Soft Lenses used for Different Replacement Intervals

Frequency of Lens Replacement	Typical Lens Care Regimen
Daily	Saline / multipurpose solution for rinsing
Weekly	Multipurpose solution
Two-weekly	Multipurpose solution
Monthly	Multipurpose solution
Three-monthly	Multipurpose solution (possibly with protein removal) or hydrogen peroxide with separate daily cleaner (possibly with protein removal)
Six-monthly or more	Hydrogen peroxide with separate daily cleaner and protein removal

SINGLE-USE TRIAL LENSES

In the case of disposable lenses, new diagnostic or trial lenses are used with each patient, and disposed of thereafter. This eliminates the risk of cross-infection from a previous wearer of the lens. It also has the advantage of eliminating the time-consuming chore of trial lens cleaning, disinfection and storage.

TRIAL LENS FITTING WITH ACCURATE PRESCRIPTION

With the ready availability of a comprehensive stock of trial lenses (Fig. 19.14), it is nearly always possible to undertake a lens-wearing trial on a prospective disposable lens patient with the required lens parameters, especially with respect to lens power.

This will, of course, allow for the most realistic subjective impression of lens wear and allow the practitioner to assess the fit of what is likely to be the final lens specification in many instances. For certain specialist fittings, such as presbyopia, trial fitting is more meaningful if the appropriate lens powers for the refractive condition of the patient are used.

LENS PARAMETERS EASY TO CHANGE

By the very nature of planned replacement, it is straightforward to modify the prescription of a patient, particularly with

Fig. 19.14 The availability of single-use diagnostic lenses allows for accurate trialling and eliminates the risk of cross-infection.

respect to changes in refractive error. From a practice management viewpoint, it is advisable to carry out a routine aftercare appointment before dispensing the next supply of lenses for the patient. Any alteration in lens power can then be made without the need to exchange unwanted lenses.

Potential Disadvantages of Planned Replacement

There are probably no clinical disadvantages in prescribing planned, as opposed to unplanned, replacement lenses. However, there are some points to bear in mind that may have negative implications.

PATIENT NON-COMPLIANCE

Soon after the introduction of disposable lenses into the market, Matthews et al. (1992) reported a higher level of complications with disposable daily-wear lenses than with 'conventional' lenses not replaced on a planned basis. This was attributed to poor lens hygiene, the use of relatively inefficacious disinfecting systems such as chlorine, patient non-compliance and lens type. The first disposable lens on the market – Acuvue (Johnson & Johnson) – was originally promoted as an extended-wear lens, and many problems could be traced to non-compliance relating to overnight lens wear. These issues have now been largely solved; Acuvue lenses are used primarily for daily wear, and chlorine solutions are no longer marketed.

Although it can now be assumed that the use of planned replacement lenses and simple lens care products (e.g. multipurpose solutions) enhances patient compliance (Claydon et al., 1996), the potential for patient non-compliance is ever present, and practitioners should be constantly alert to this potential problem (see Chapter 42).

Nilsson (1997) suggested that, because disposable lenses are discarded so often, patients and practitioners can become complacent about lens care. Daily cleaning and disinfection remain a vital part of safe lens wear for any reusable lens, regardless of replacement frequency. Since the available parameters of disposable lenses, as opposed to prescription or custom lenses, are limited, practitioners may also be guilty of 'sloppy fitting' (Nilsson, 1997). It has also been suggested that disposable lens wearers may seek to solve a problem that would otherwise be in need of professional attention by simply changing the lens (Gasson and Morris, 1992).

Dumbleton et al., 2011 demonstrated that two-thirds of silicone hydrogel lens wearers did not comply with the minimum recommended replacement frequency of the manufacturer and wearers of lenses designed for 2-weekly replacement stretched the replacement interval of their lenses to a greater degree than did wearers of lenses designed for once-weekly replacement. They also found that failing to replace lenses when recommended and failing to rub and rinse lenses were associated with a higher rate of patient-reported contact lens problems.

It may be difficult to manage infrequent lens wearers via a planned replacement system simply because the rate of lens spoilation will be lower and more variable compared with that in full-time wearers. Also, compliance with the recommended replacement schedule may become problematic if the lenses are discarded at irregular intervals (Saitou et al., 2005). For part-time wearers, therefore, daily disposable lenses are the preferred choice.

Provided lens fitting, aftercare and patient education are of a good standard, there are no compelling reasons for avoiding planned replacement, as long as the required parameters are available.

QUALITY AND REPRODUCIBILITY ISSUES

Efron and Veys (1992) observed small defects in early-generation disposable lenses and suggested that these can cause complications. With any lens replaced at least monthly, it is not practical for each lens to be inspected, either prior to insertion or while in the eye of the patient. For planned replacement to be successful it is a requirement that lenses are sufficiently consistent in quality such that the patient will not notice any change in comfort, fit or visual acuity from lens to lens. Certainly, the various types of moulding systems used to produce most disposable lenses are developed on the principle of building quality into the product, as the traditional manual methods previously used by manufacturers to examine conventional lenses would not be cost-effective with a mass-produced lens.

Wider quality issues are also important when the patient is using many lenses each year. Consistency of packaging and labelling are of great significance when the patient is supplied with unopened packages. If patients find that some blister packs are empty, dry or contain more than one lens, their confidence in the product is likely to be reduced.

Notwithstanding the above considerations, the recent literature is free of descriptions of complications attributable to poor disposable lens quality; nevertheless, patients should be advised to inspect visually all lenses prior to insertion and discard any lenses exhibiting surface or edge defects, or any that are persistently uncomfortable, cause significant eye redness or provide poor vision.

Practitioners can be reassured that the processes used to manufacture disposable lenses result in consistent lens parameters. Young et al. (1999) evaluated eight reusable lens types and found reproducibility to be good for power, base curve and centre thickness, and acceptable for total diameter. The same researchers found adequate reproducibility of frequent replacement soft toric lenses (Young et al., 2001).

Determining the Appropriate Lens Replacement Frequency

It is not straightforward to identify the ideal lens replacement frequency for a given patient. An appropriate replacement interval can be chosen from one of the standard replacement intervals formulated for various products by contact lens manufacturers. Such a decision is made after consideration of the desired pattern of wear and contact lens history of the patient. There are essentially three key reasons why a greater frequency of lens replacement may be required: excessive lens deposition, recurrence of ocular complications thought to be related to lens deposition, and poor lens replacement compliance (Dumbleton et al., 2011). It is advisable, for both legal and practical reasons, to use the replacement interval(s) for a given lens recommended by the manufacturer as a maximum.

Practice Management Issues Relating to Planned Soft Lens Replacement

For planned lens replacement, practitioners need to employ systems for tracking and managing lens stocks, delivering lenses and solutions to patients, sending recall reminders and arranging aftercare visits. Specialised approaches to financial management are required. In many instances, these approaches nurture a close working relationship between practitioners and manufacturers.

LENS DELIVERY SYSTEMS

Two main methods for managing the implementation of planned lens replacement systems can be adopted: manufacturer-driven systems and practice-driven systems.

Manufacturer-driven Systems

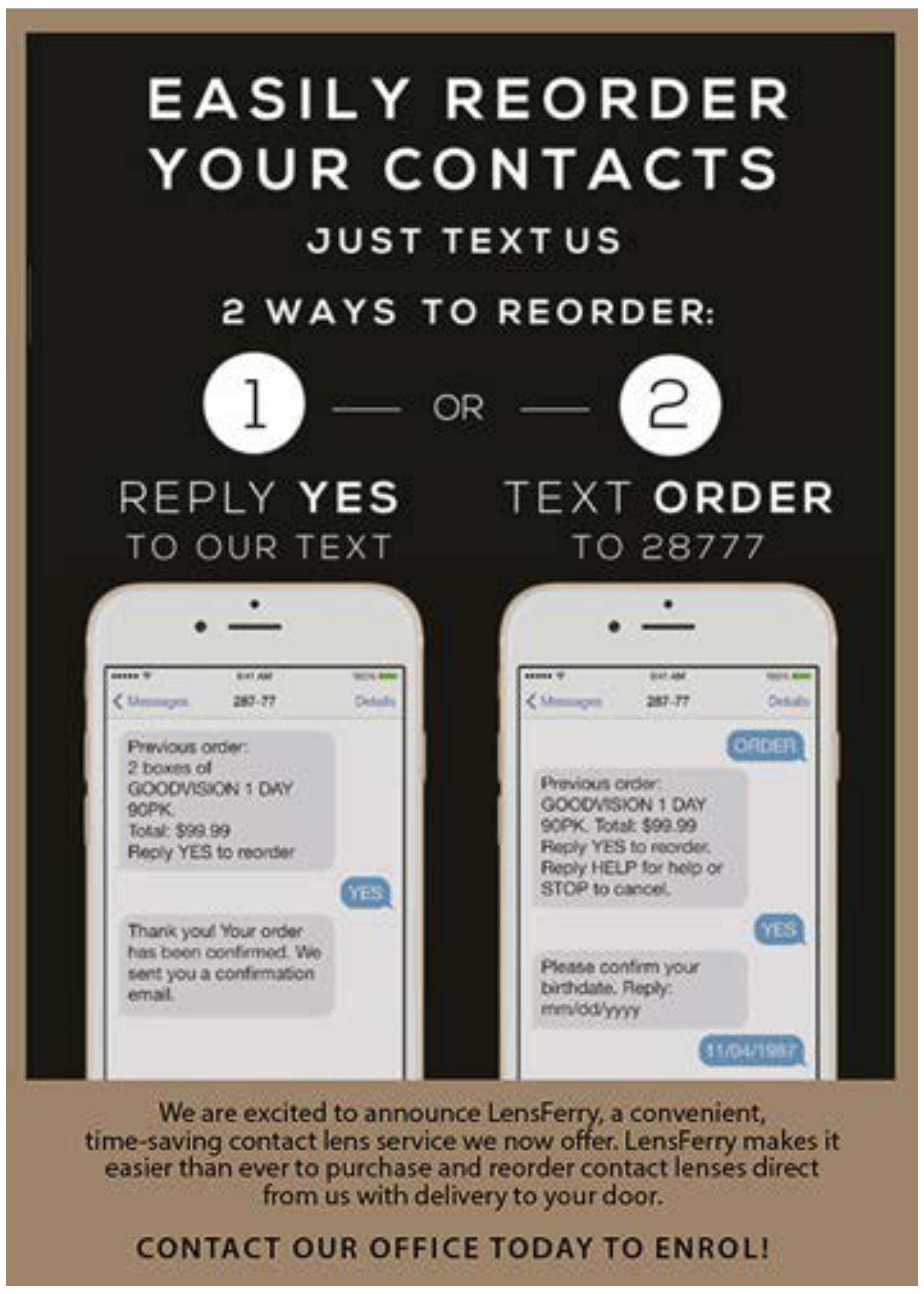
The names of new patients are registered with the manufacturer by the practice along with relevant prescription details. Depending on the lens type, there may also be an option to select a frequency of lens delivery to the practice; for example, monthly replacement lenses may be supplied to the practice in 3- or 6-month quantities. Once the patient is registered, fresh supplies of lenses will be automatically dispatched to the practice until countermanded.

Manufacturers have, in some cases, branded their systems to promote the service provided. The main benefit to practices is reduced administration. Simple computer programs run the systems, and the arrival of a new supply of lenses for a given patient acts as a trigger for the practice to recall that particular lens wearer. In many countries, such systems complement the method by which many patients pay for frequent replacement lenses – namely, monthly direct payment from their bank account to the account of the practice. In this way, both payment and regular lens supply are automated and compliance with the designated replacement schedule is encouraged.

Some manufacturers have expanded their service to include direct delivery of lenses and lens care products (so-called ‘bundling’) to the home address of the patient (Fig. 19.15). The increased convenience afforded by this approach is promoted as a means of retaining the custom of the patient for replacement lenses, given the growth of non-practice sources of supply such as direct mail and the internet (see below). A further recent development is the provision by some manufacturers of replenishment systems designed for mobile devices. These may allow branding of the portal by the practice to maintain continuity of the patient relationship and offer a direct alternative to third-party internet resellers (Fig. 19.16).

VISION LINK
Focus
SOLO care
Focus DAILIES
AOSEPT

Fig. 19.15 Planned replacement enables practices to provide lenses and lens care products in a convenient bundle.



EASILY REORDER YOUR CONTACTS

JUST TEXT US

2 WAYS TO REORDER:

1 — OR — 2

REPLY **YES** TO OUR TEXT

TEXT **ORDER** TO 28777

Previous order: 2 boxes of GOODVISION 1 DAY 90PK. Total: $99.99 Reply YES to reorder

YES

Thank you! Your order has been confirmed. We sent you a confirmation email.

ORDER

Previous order: GOODVISION 1 DAY 90PK. Total: $99.99 Reply YES to reorder. Reply HELP for help or STOP to cancel.

YES

Please confirm your birthdate. Reply: mm/dd/yyyy

11/04/1987

We are excited to announce LensFerry, a convenient, time-saving contact lens service we now offer. LensFerry makes it easier than ever to purchase and reorder contact lenses direct from us with delivery to your door.

CONTACT OUR OFFICE TODAY TO ENROL!

Fig. 19.16 A resupply service enabling practices to offer patients convenient re-ordering on their mobile devices. (Courtesy of CooperVision.)

Practice-driven Systems

If a manufacturer-driven system is not employed, an in-house system is required to ensure the timely purchase of replacement lenses and recall of patients. With larger patient bases, the amount of stock involved can be quite large and adequate storage space is often an issue. On the other hand, bulk purchasing may allow practices to secure preferential terms from suppliers. A practice operating its own system is also in complete control of the process and less vulnerable to any

TABLE 19.3 Parameter Availability for Commonly Available Disposable Daily-wear Lenses

Lens Type	Diameters (mm)	Base Curves (mm)	Powers (D)
One- to two-weekly and monthly sphere	14.0–14.5	8.2–9.3	+15.00 to −20.00
One- to two-weekly and monthly toric	14.0–14.6	8.3–9.2	+10.00 to −11.00DS −0.75 to −5.75DC Axes 5 to 180 (5° steps)
One- to two-weekly and monthly bi/multifocal	14.0–14.5	8.3–8.9	+6.00 to −10.00
One- to two-weekly and monthly tint	14.0–14.5	8.6–8.9	+6.00 to −8.00

*Excludes private labels and alternative branding of the same lens, and lenses primarily intended for extended wear.

for ASTIGMATISM
AIR OPTIX
breathable contact lenses*
Alcon
a Novartis company
A
BAUSCH+LOMB
PureVision 2
For Astigmatism
6 Soft Contact Lenses
B
Biofinity toric
Aquaform Comfort Science
3 contact lenses
CooperVision
C
ACUVUE OASYS
BRAND CONTACT LENSES
FOR ASTIGMATISM
WITH HYDRACLEAR PLUS
6 Lenses
UV BLOCKING
D

Fig. 19.17 Examples of reusable toric silicone hydrogel contact lenses: (A) Air Optix for Astigmatism (Alcon); (B) PureVision 2 for Astigmatism (Bausch & Lomb); (C) Biofinity toric (CooperVision); (D) Acuvue Oasys for Astigmatism (Johnson & Johnson Vision Care).

manufacturer supply problems. In some markets it is possible to bulk purchase product without taking delivery until supply for an individual patient is required. This is referred to as owning a 'virtual stock' or 'lens banking'. It saves space, means there is no need to manage the stock in respect of powers and allows the prepurchase of lenses not usually stocked, such as torics and multifocals.

LENSES AVAILABLE FOR PLANNED REPLACEMENT

It is possible to fit a substantial majority of soft lens patients with lenses replaced at least monthly (Table 19.3). The principal lens types – such as spherical (see Fig. 19.13), toric (Fig. 19.17), multifocal (Fig. 19.18) and tinted (Fig. 19.19) – are available in several alternative replacement frequencies and increasingly in silicone hydrogel materials, as illustrated in Figs. 19.13 and 19.17–19.19. In fact, none of the major international contact lens manufacturers has launched a hydrogel planned replacement lens for some years.

Patients for whom the desired lens replacement frequency is unavailable are now mainly restricted to those with extreme prescriptions. Patients needing a lens diameter that is smaller than usual, say 13.50 mm, are also less easily fitted with the current range of disposable lenses, most of which are at least 14.00 mm total diameter. However, 3-monthly replacement potentially allows manufacturers to offer custom or prescription lenses, so that even outlying parameter requirements can be met in many cases.

PRACTICE LOGISTICS

There is no doubt that planned replacement can generate considerable extra workload in a practice. The main issues are stock levels, patient aftercare and recall and payment.

As an example, a practice with 500 patients using 2-weekly disposable lenses will handle over 4000 six-packs of lenses per annum, ignoring new fits, or over 80 lens packs per week on average. Five hundred patients will also require 500–1000 aftercare appointments, depending on the preference of the

Fig. 19.18 Examples of reusable bi/multifocal silicone hydrogel contact lenses: (A) Air Optix Multifocal (Alcon); (B) PureVision 2 for Presbyopia (Bausch & Lomb); (C) Biofinity multifocal (CooperVision); (D) Acuvue Oasys for Presbyopia (Johnson & Johnson Vision Care).

Fig. 19.19 Example of reusable tinted silicone hydrogel contact lens. Air Optix Colors (Alcon).

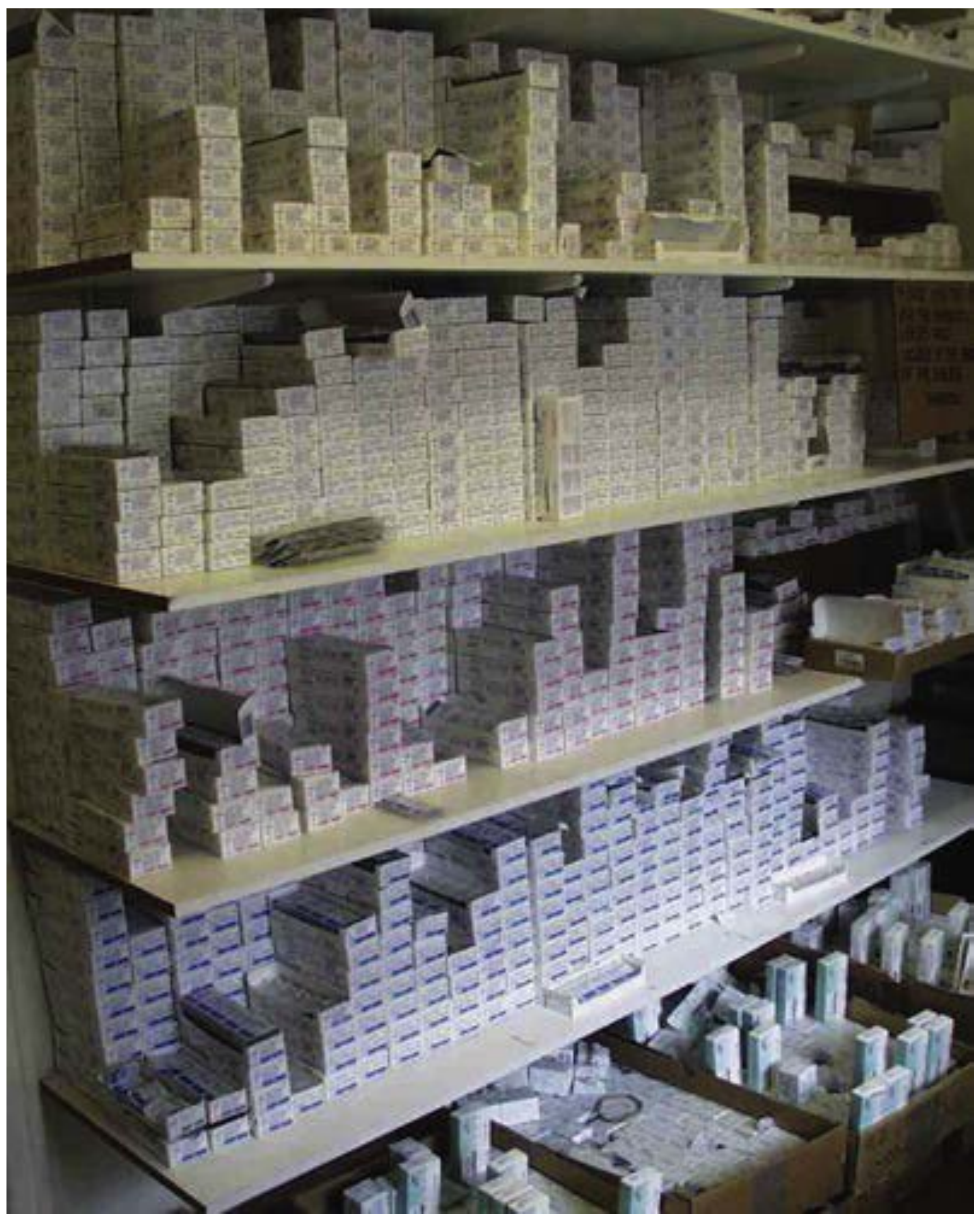


Fig. 19.20 Practices with large patient bases will need to manage, and find space for, extensive stocks of planned replacement lenses.

practitioner. This is perhaps as much as 30% of annual available chair time. If patients collect their supplies quarterly, practice staff will deal with nearly 40 collections per week.

Assuming the above level of activity, a reasonable stock, or inventory, of lenses will need to be kept in the practice to ensure good service to patients, and such stocks can consume a considerable amount of space (Fig. 19.20).

There are several approaches to deciding what levels of stock to maintain. The simplest involves keeping a few boxes of each parameter or 'stock kept unit' (commonly referred to by manufacturers as the acronym 'SKU'). As next-day delivery is often available, large numbers of lenses do not need to be stocked, although several spherical disposable lens brands have parameter ranges of over 100 SKUs. Practices may wish to weight their stock towards the more commonly occurring prescriptions, such as the range from −1.00 to −5.00 D. With very large patient bases, it may be helpful to consult with suppliers, who can advise on an appropriate in-practice stock holding based on statistical stock models used to manage their own inventory.

Practices that are computerized may wish to model their stock on the actual prescriptions of their patient base. This approach can be tied in with the aftercare recall system. Due allowance needs to be made for unpredictable purchasing

Fig. 19.21 Diagnostic lenses allow for convenient and accurate fitting assessment.

patterns, which can arise, for example, ahead of holiday periods. As well as holding sufficient stock for purchase, an adequate number of trial or diagnostic lenses are needed for ongoing fitting (Fig. 19.21).

COST TO THE PATIENT

Efron et al. (2012) constructed a cost-per-wear (CPW) model to assist practitioners and patients in considering the cost implications of various lens replacement frequencies (daily, 2-weekly and monthly), tailored to the wearing habits of individual patients. The CPW is a simple calculation of the total cost of lenses (and solutions for non-daily lens replacement) over a 12-month period divided by an estimate of the number of days that lenses will be worn over 12 months. For the full-time wearer, the difference in CPW between 2-weekly and monthly replacement lenses was small. For part-time wearers, daily disposable lenses were usually cheaper than monthly replacement lenses (Efron et al., 2012).

FINANCIAL MANAGEMENT

The clinical benefits of planned replacement have been described above. It would be remiss not to mention the commercial benefits that this modality also delivers. Patients changing their lenses regularly, particularly if wearing disposable lenses, will generate a more predictable practice cash flow.

Contact lenses are often promoted as 'practice builders' since they usually require more practice visits and a more detailed appreciation by the patient of the professional skills required to maintain successful wear. This encourages greater loyalty than for spectacle-wearing patients. By reducing complications and increasing patient satisfaction, frequently replaced lenses further enhance the business benefits of developing a large base of contact lens wearers.

ALTERNATIVE SUPPLY ROUTES

The issue of non-optical-practice supply now affects virtually all contact lens types, although disposable lenses are particularly susceptible to third-party distribution given the brand awareness that many of these products have with the public. In the USA, the Fairness to Contact Lens Consumers Act (2004) is intended to allow contact lens wearers the freedom to shop around for their contact lens supplies.

The critical issue here is that it is in the public interest to have a system of lens supply that guarantees the ongoing preservation of the ocular health of lens wearers. A system that provides no disincentives to patients to continue to purchase lenses for many years without having their eyes examined poses a significant public health risk. Contact lens wearers who purchase lenses online have been shown to be at greater risk of microbial keratitis (Stapleton et al., 2008).

Notwithstanding the role of regulatory authorities in discharging their responsibilities for public health and safety, there are strategies that practitioners can employ to retain control of lens supply and to link this to patient care. Fee splitting – where materials are charged at relatively low mark-ups on cost, and these charges are separated from professional fees – helps demonstrate to patients that most of the cost involved in wearing contact lenses is attributed to the professional time involved. Home delivery plans, perhaps operated on behalf of the practice by a supplier, enable practitioners to match the perceived convenience of mail order and internet supply companies. Large practices or group practices may be able to come to an arrangement with manufacturers so that lenses and solutions supplied by that manufacturer are 'rebranded' prior to delivery. The rebranding (or so-called 'own-labelling' or 'private labelling') facilitates an association of the products with the practice and thereby serves to enhance patient loyalty. However, as the lens specifications cannot be altered, it is relatively straightforward to determine the original brand and therefore purchase the original brand elsewhere if the patient desires.

Conclusion

Planned contact lens replacement enhances clinical performance, increases convenience and promotes practice profitability. Planned soft lens replacement will continue to represent a viable approach to prescribing contact lenses for the foreseeable future; however, some countries are now trending strongly in favour of daily disposables and their eventual dominance over lenses with longer replacement intervals seems likely in many developed markets.

ACKNOWLEDGEMENTS

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Access the complete references list online at http://www.expertconsult.com.

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20

Planned Replacement Rigid Lenses

CRAIG A WOODS

Introduction

The perceived advantages of rigid lenses, compared with soft lenses, include increased corneal oxygenation (Efron and Ang, 1990), longer life expectancy (Atkinson and Port, 1989), reduced risk of microbial keratitis (Dart et al., 2008; Stapleton et al., 2008), fewer toxic/allergic complications (Hamano et al., 1988) and superior vision in cases of corneal astigmatism. Many clinicians believe that rigid lenses should be considered the lens of first choice (Dart et al., 1991).

It has been shown that, as soft lenses age, their physical and clinical performance deteriorates, resulting in reduced comfort (Poggio and Abelson, 1993), reduced vision (Gellatly et al., 1988) and decreased wettability (Guillon et al., 1992). This has resulted in the wide acceptance of planned replacement for soft contact lenses (Jones, 1994).

The concept of planned replacement for soft contact lenses is well established and the benefits of regular replacement of soft contact lenses are covered in Chapter 19. The regular replacement of rigid lenses gives rise to similar benefits. Rigid lenses can develop deposits such as the presumed protein haze shown in Fig. 20.1. The lens surface can become scratched over time (Fig. 20.2), necessitating lens polishing or replacement. Fine splits (Fig. 20.3) can occur at the edge of rigid lenses, requiring lens replacement. Another ageing problem with rigid lenses is the development of crazing – that is, the appearance of interconnecting cracks that can extend deep into the lens (Fig. 20.4). Crazing predisposes the lens to the development of secondary deposits, and the lens can become uncomfortable owing to the crazing and/or the existence of deposits (Lembach et al., 1988). Crazing can also be due to problems occurring during manufacture (McLauchlin and Schoessler, 1987) and is not often seen today. The aim of regular lens replacement is to avoid such adverse occurrences.

Life Expectancy of Rigid Contact Lenses

The perception might be that rigid lenses have a longer life than soft contact lenses. Due to their negligible water content and high modulus of elasticity, rigid materials lend themselves well to prolonged life. The method of manufacturing (lathe cutting) is relatively labour intensive and costly compared with that of manufacturing disposable soft lenses, which raises questions of the cost-effectiveness of regular rigid lens replacement.

The literature reports a wide range for the life expectancy for rigid lenses. Atkinson and Port (1989) concluded that they last between 2 and 3 years and Yokota et al. (1992) estimated the life of rigid lenses to be between 5 and 10 years. Both of these reports reflect the clinical opinions of the authors with limited evidence-based data. Jones et al. (1996) analysed data from 600 patients and were able to show that the life expectancy of rigid lenses was related to the material's oxygen permeability (Dk). The mean life expectancy of rigid lenses was found to be 20 ± 17 months for low-Dk materials, 16 ± 13 months for mid-Dk materials, and 9 ± 8 months for high-Dk materials (Fig. 20.5).

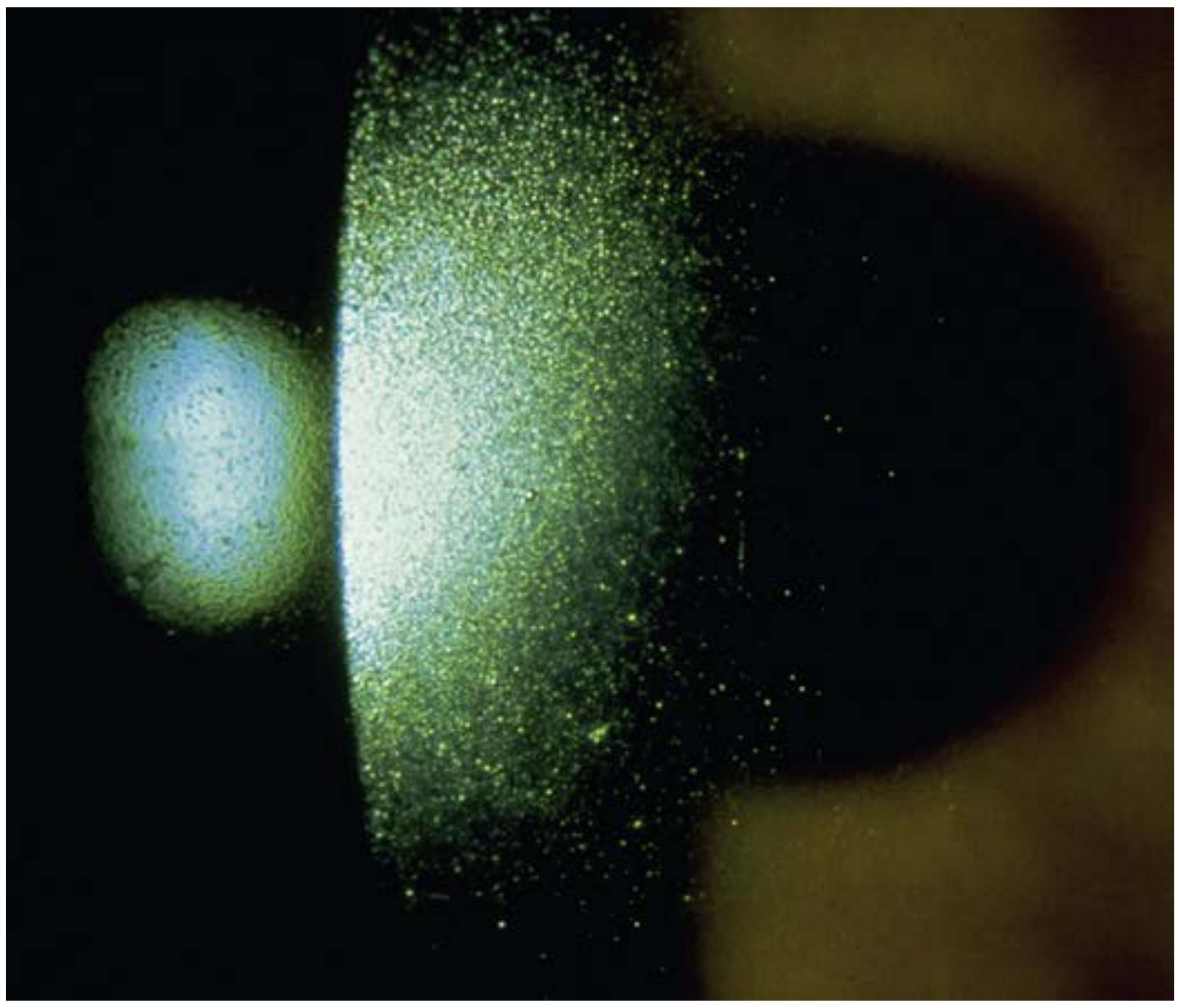

Fig. 20.1 Presumed protein haze on a rigid lens worn on a non-replacement basis. (Courtesy of Arthur Back, Bausch & Lomb Photo Library.)

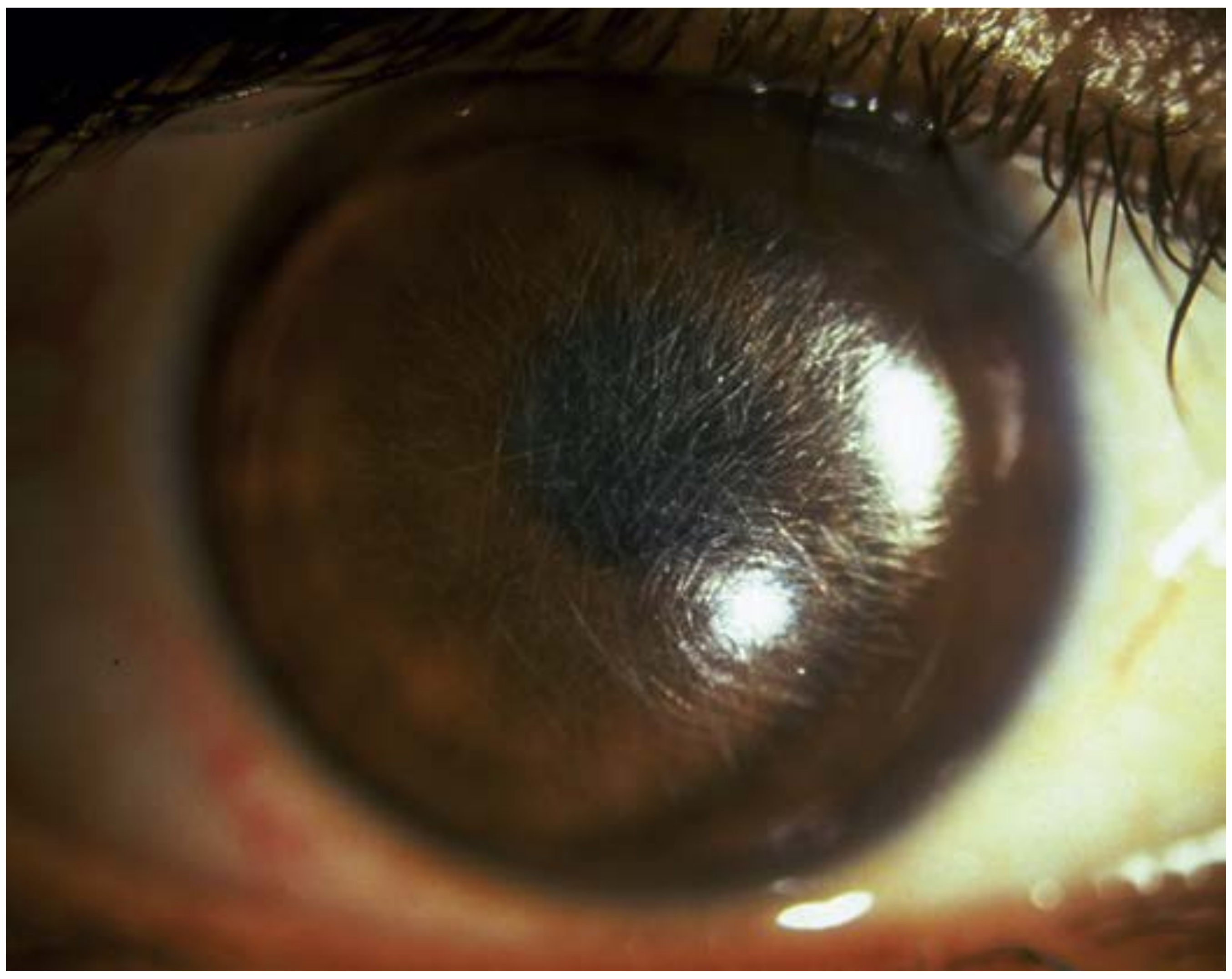

Fig. 20.2 Scratches on the surface of a rigid lens worn on a non-replacement basis.

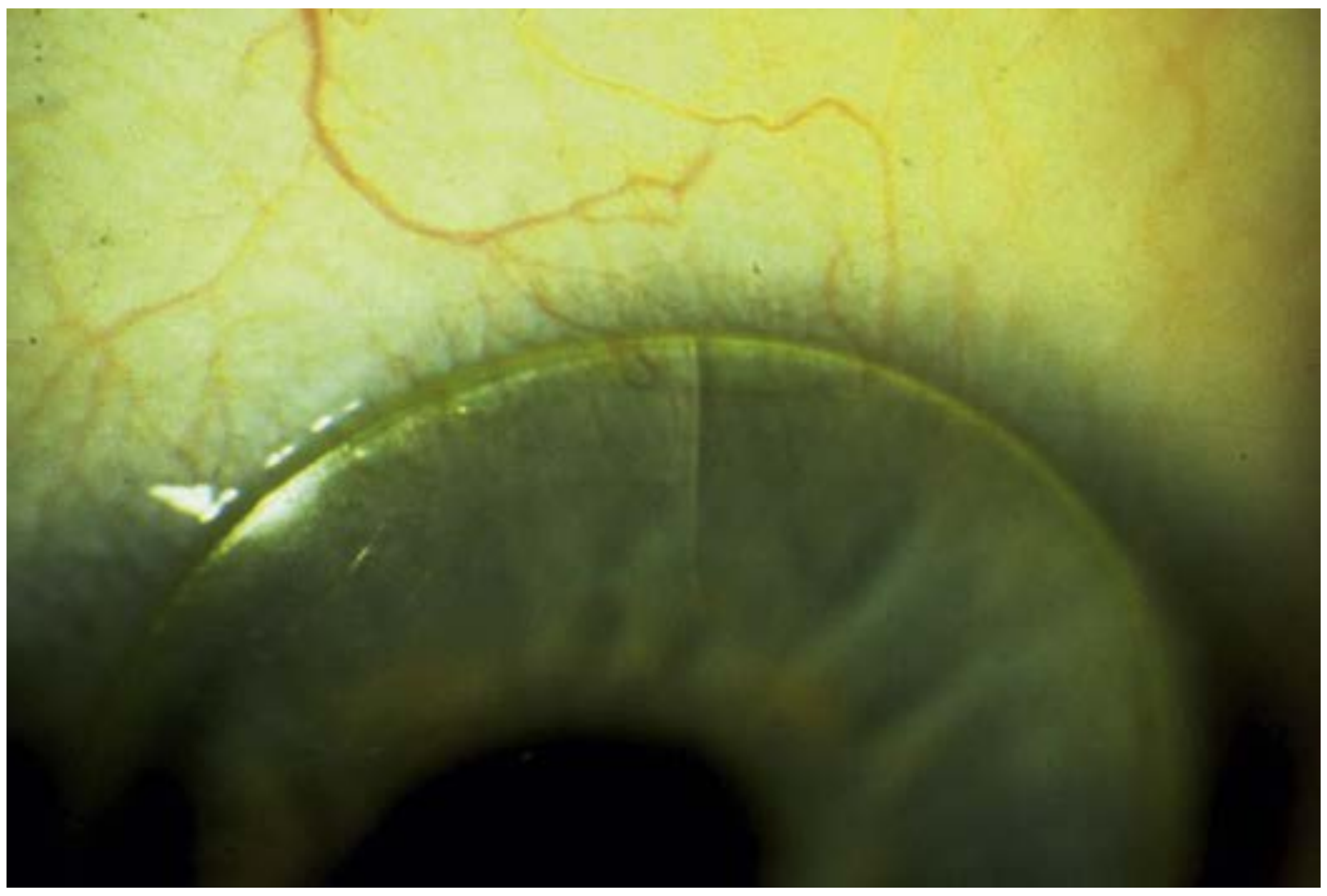

Fig. 20.3 Fine split at the edge of a rigid lens worn on a non-replacement basis. (Courtesy of Lyndon Jones, Bausch & Lomb Slide Library.)

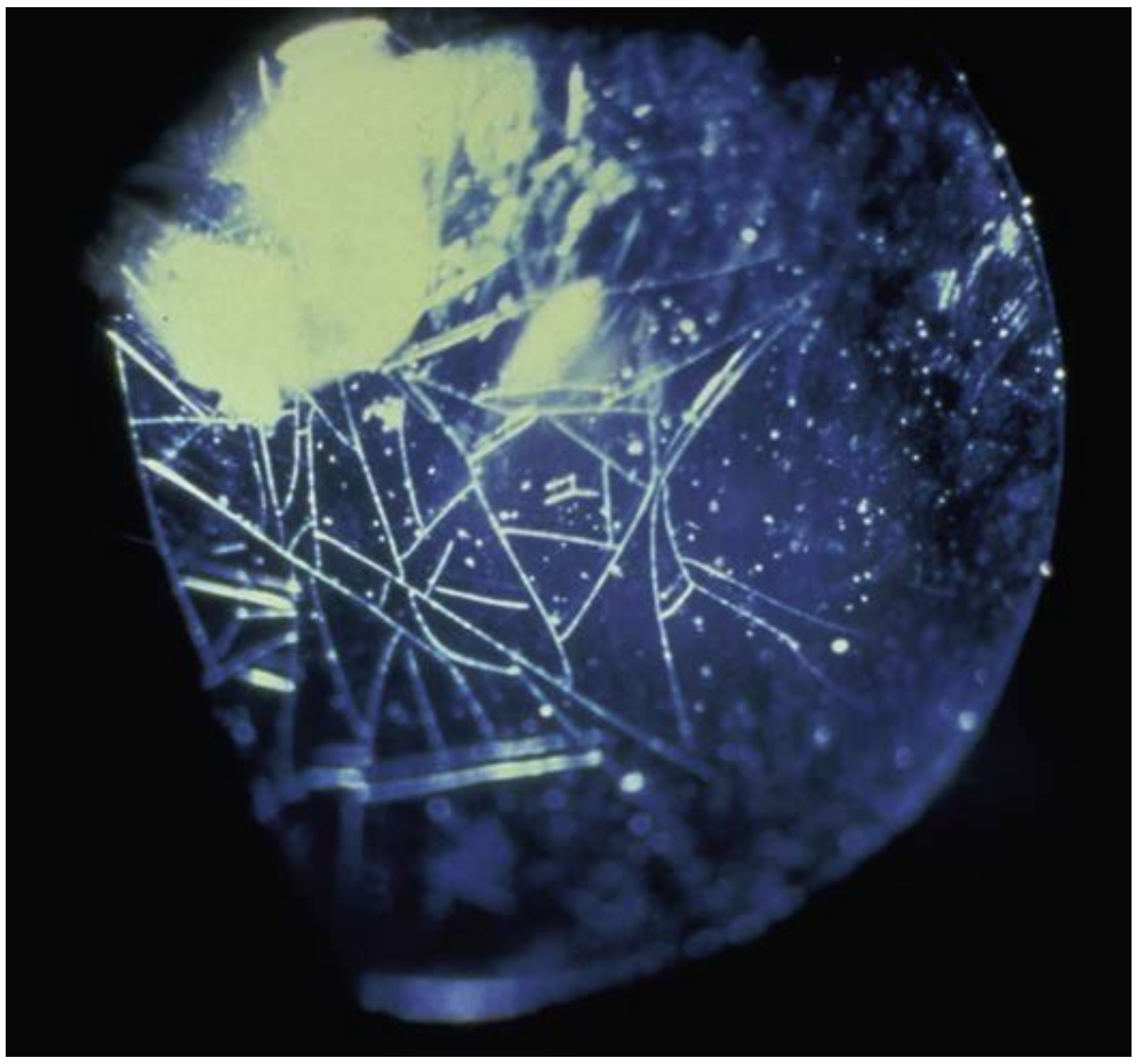

Fig. 20.4 Crazing on the surface of a rigid lens worn on a non-replacement basis.

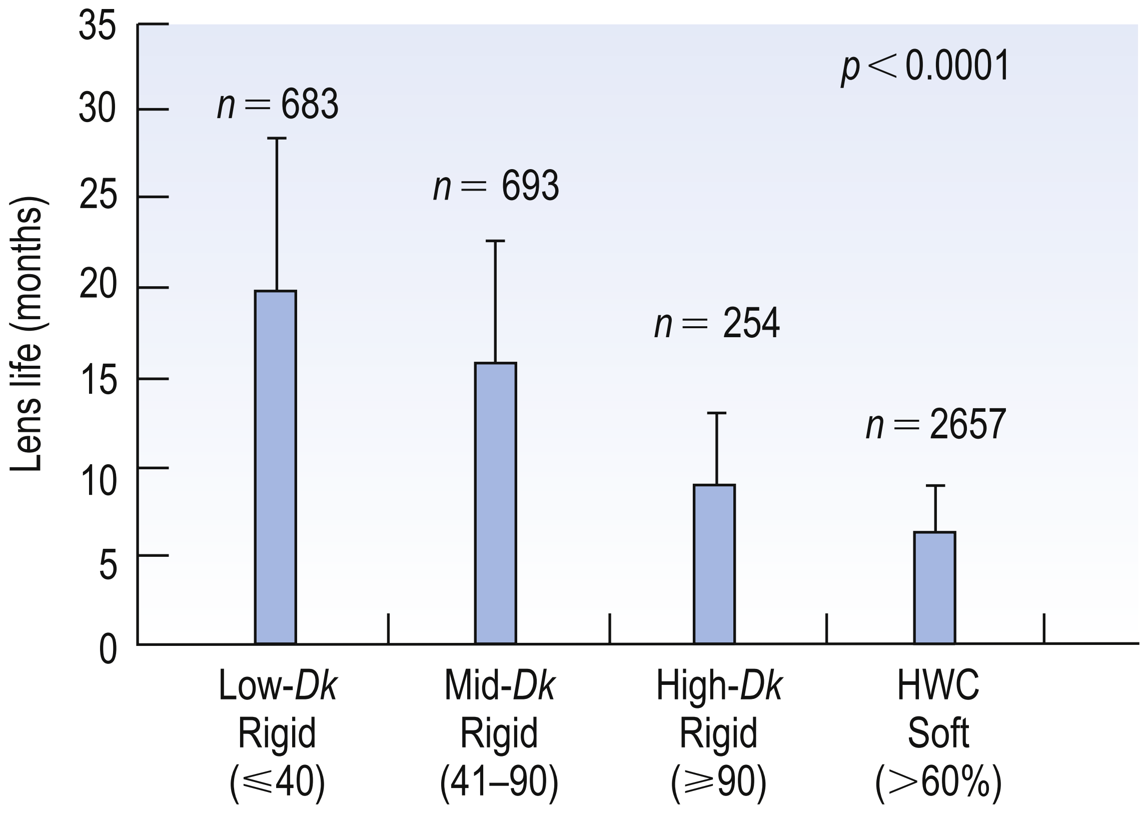

Fig. 20.5 Mean lens life for various contact lens materials. Ranges for low-, mid- and high-Dk materials are shown in brackets. HWC = high-water-content materials.

In the same study, the life expectancy of high-water-content soft lenses was found to be 6 ± 5 months. This compared well with other published data (Jones, 1990), which also established an expected lifespan for high-water-content soft lenses of about 6 months.

All contact lenses should have sufficient oxygen transmissibility (Dk/t) to maintain near-normal corneal metabolism. A Dk/t of 24 Barrer/cm is required from a lens worn on a daily-wear basis, for an average cornea (Holden and Mertz, 1984). High-Dk materials have been shown to result in reduced hypoxia and hypercapnia (Efron and Ang, 1990), reduced stromal acidosis (Polse et al., 1992), a lower overall complication rate (Hamano et al., 1988) and reduced binding of Pseudomonas aeruginosa to the corneal surface (Imayasu et al., 1994). The conclusion from these studies is that, from a physiological standpoint, contact lenses should be made from high-Dk materials wherever possible.

The study by Jones et al. (1996) demonstrated that lenses manufactured from higher-Dk materials have a reduced life expectancy when compared with lower-Dk materials. This is not unexpected, since lenses made from high-Dk materials are less mechanically stable (i.e. subject to warpage) and more prone to surface scratching (Tranoudis and Efron, 1996) than lenses made from low-Dk materials. Table 20.1 indicates that lenses manufactured from materials with nominally quoted uncorrected Dk values of ≥90 Barrer should last approximately 9 months, compared with 20 months for lenses with a Dk of ≤40 Barrer.

All contact lenses demonstrate a deterioration in performance with age. Although this has been clearly demonstrated with soft lenses (Poggio and Abelson, 1993), studies of rigid lenses also show a gradual deterioration in wettability (Guillon et al., 1995) and visual performance (Jones et al., 1995), and an increase in surface scratching and deposition (Allary et al., 1989; Guillon et al., 1995; Jones et al., 1995), irrespective of Dk or material type.

It was common with PMMA materials to 'prolong' the life of the lens by repolishing the lens surfaces. Some clinicians believe that repolishing techniques can also be applied to prolong the life of rigid lenses; however, caution should always be exercised with this procedure as overpolishing can lead to reduced surface wettability and ultimately result in reduced comfort and visual performance (Grohe et al., 1988) (Fig. 20.6).

Regular Replacement of Rigid Lenses

The concept of regular replacement of rigid lenses was first considered by Grohe in 1992. He concluded that the major problem with the introduction of such systems would be the increased cost to the patient with little obvious benefit (Grohe, 1992). However, if it is accepted that: (1) higher-Dk materials should be fitted for clinical reasons, (2) such lenses have a reduced life expectancy and (3) all lenses show a deterioration in performance with age, then the planned replacement of high-Dk rigid lenses would appear to be a logical modality for practitioners and patients to adopt. The benefits of such a schedule have been demonstrated for lenses worn on a daily-wear basis (Guillon et al., 1995) (see Table 20.1). Allary et al. (1989) reported that surface scratching and deposition on rigid lenses increase with lens age; however, this study was not controlled or designed to investigate

TABLE 20.1 Time Span for the Development of Adverse Changes to Various Parameters of the Contact Lens and Eye during Rigid Lens Wear

Parameter	Time Span	Mode of Wear	Reference
Life expectancy	5–10 years	Daily wear	Yokota et al., 1992
Life expectancy	2–3 years	Daily wear	Atkinson and Port, 1989
Life expectancy*	20 months	Daily wear	Jones et al., 1996
Life expectancy†	16 months	Daily wear	Jones et al., 1996
Corneal staining	12 months	Daily and extended wear	Woods and Efron, 1996a
Conjunctival staining	12 months	Extended wear	Woods and Efron, 1996b
Limbal hyperaemia	12 months	Daily wear	Woods and Efron, 1996a
Mucus coating	12 months	Daily and extended wear	Woods and Efron, 1996a
Surface deposition	12 months	Daily wear	Woods and Efron, 1996a
Tarsal changes	12 months	Daily wear	Woods and Efron, 1996a
Life expectancy‡	9 months	Daily wear	Jones et al., 1996
Surface drying	9 months	Daily wear	Woods and Efron, 1996a
Surface scratching	9 months	Daily and extended wear	Woods and Efron, 1996a
Surface wetting	9 months	Daily wear	Woods and Efron, 1996a
Lens binding	6 months	Extended wear	Woods and Efron, 1996b
Surface deposition	6 months	Daily wear	Guillon et al., 1995
Surface wetting	6 months	Daily wear	Guillon et al., 1995

*Low-Dk materials.
†Mid-Dk materials.
‡High-Dk materials.

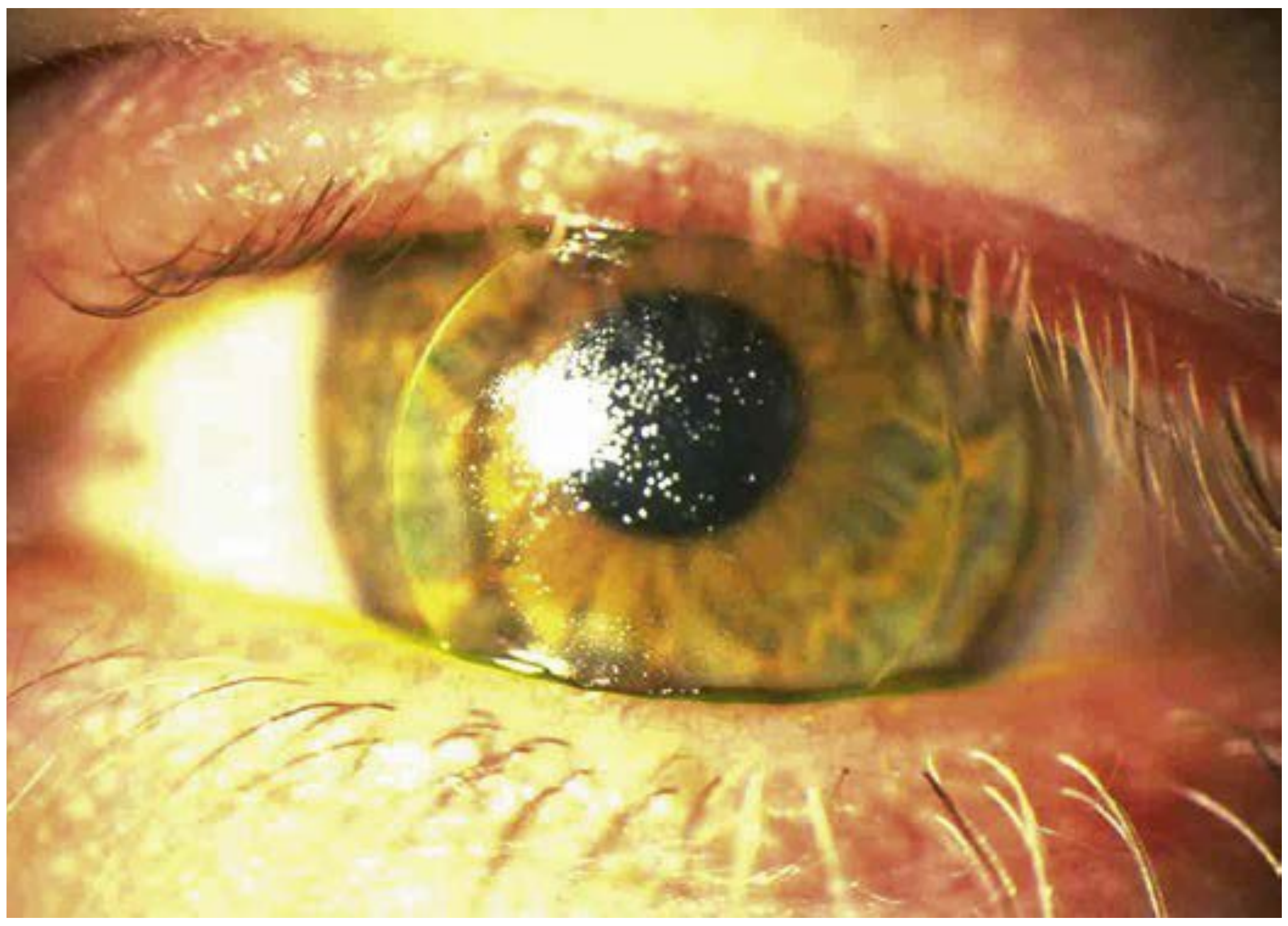

Fig. 20.6 Rigid lens surface displaying the effects of overpolishing.

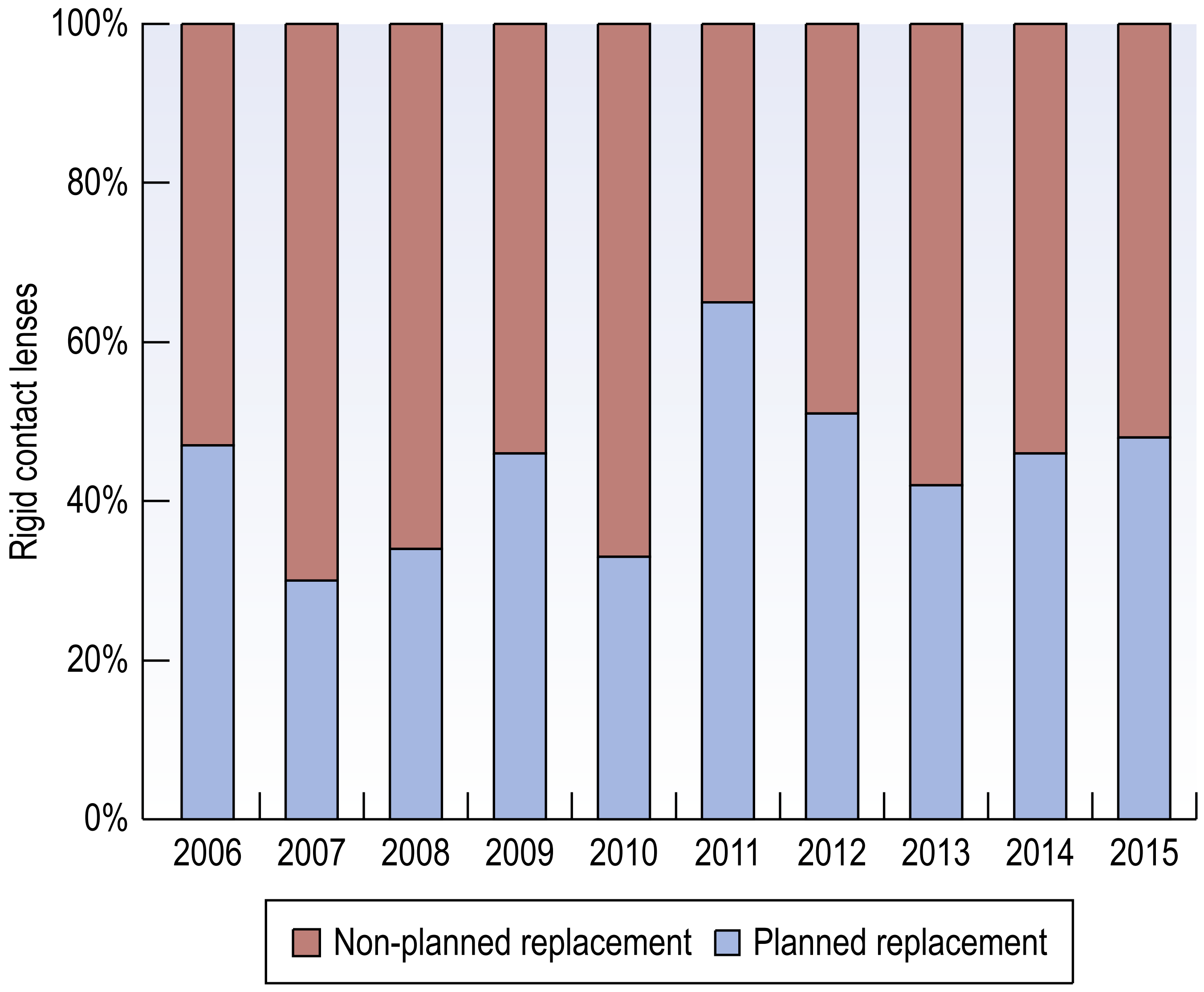

Fig. 20.7 Rigid contact lenses fitted on a planned replacement and non-planned replacement basis across the world between 2006 and 2015.

lens ageing, and their comments were an aside to the actual purpose of their study.

Grohe (1992) considered the above issues and expressed concern that rigid contact lens disposability might be introduced for marketing rather than clinical reasons. Hannon (1990) expressed the view that there were tremendous benefits in regularly replacing rigid lenses from a marketing point of view, which patients would find an acceptable concept.

The concept of planned replacement has not been embraced from a marketing perspective, nor have any specific planned replacement products been developed or promoted. Despite this, contact lens prescribing data gathered from around the world demonstrates that, between 2006 and 2015, about 40% of rigid lenses have been prescribed on a planned replacement basis (Fig. 20.7). In 2015 the proportion of rigid lenses prescribed on a planned replacement schedule was 48% overall, although there were significant differences between nations (Fig. 20.8) (Morgan et al., 2016). Efron et al. (2013) reported that 7% of rigid lenses were replaced more frequently (i.e. 2-weekly or monthly).

Advantages of Regular Replacement of Rigid Lenses

Woods and Efron (1996a, b) investigated the effects of planned replacement of rigid lenses on the integrity of the lens and the anterior ocular structures. In a masked, controlled and randomized experiment, these authors compared a group of rigid lens wearers on a planned replacement basis with a control group who were not scheduled to replace their rigid lenses over a 12-month period. This investigation was performed with rigid contact lenses worn on a daily-wear basis (Woods and Efron, 1996a) and on an extended-wear basis (Woods and Efron, 1996b).

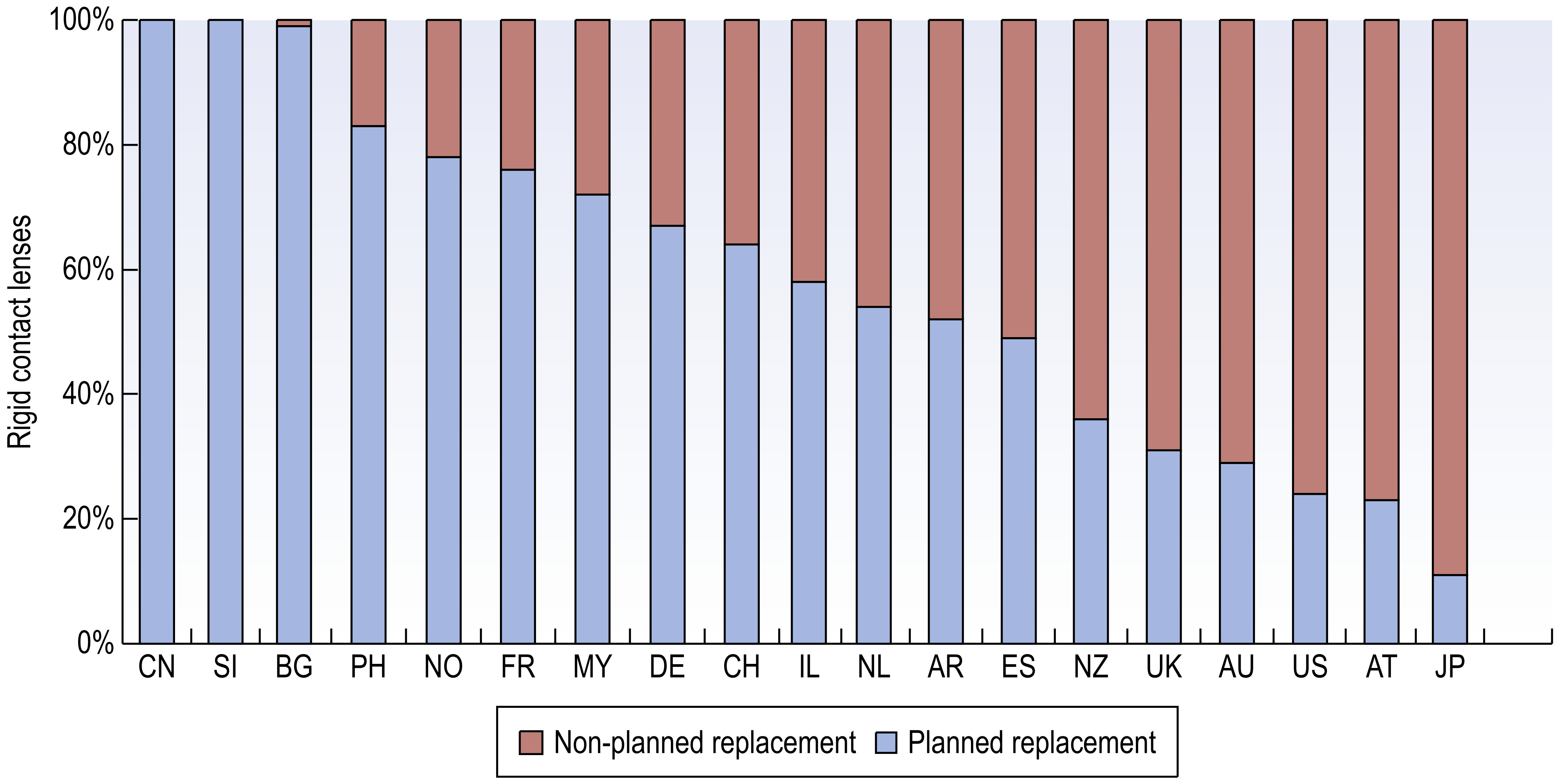

Fig. 20.8 Planned replacement rigid lenses prescribed in 19 countries in 2015. Country codes: AR= Argentina; AT= Austria; AU= Australia; BG = Bulgaria; CH= Switzerland; CN = China; DE= Germany; ES= Spain; FR= France; IL= Israel; JP = Japan; MY= Malaysia; NL= Netherlands; NO = Norway; NZ= New Zealand; PH = Philippines; SI= Slovenia; UK= United Kingdom; US= United States.

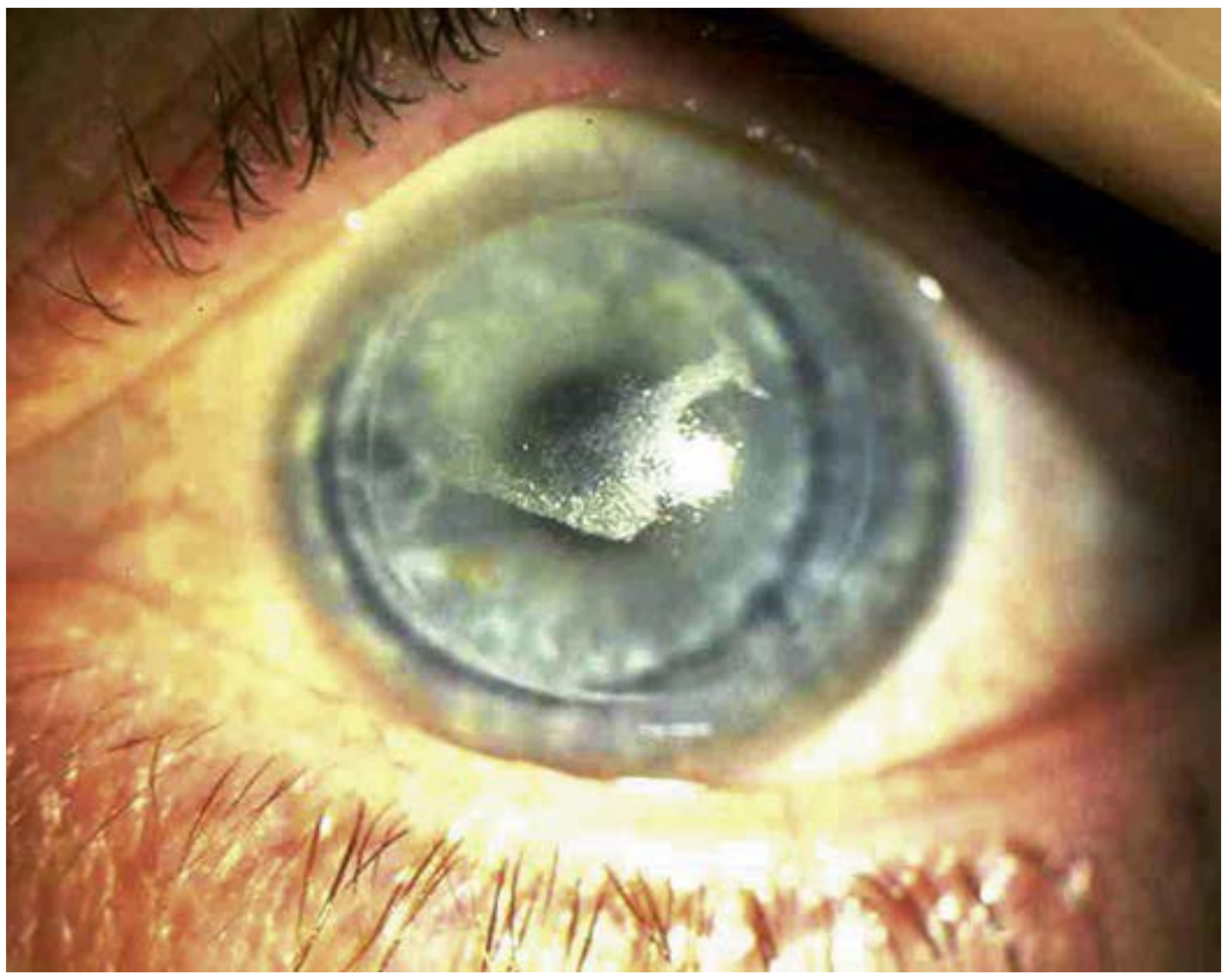

Fig. 20.9 Rigid lens with a non-wetting surface.

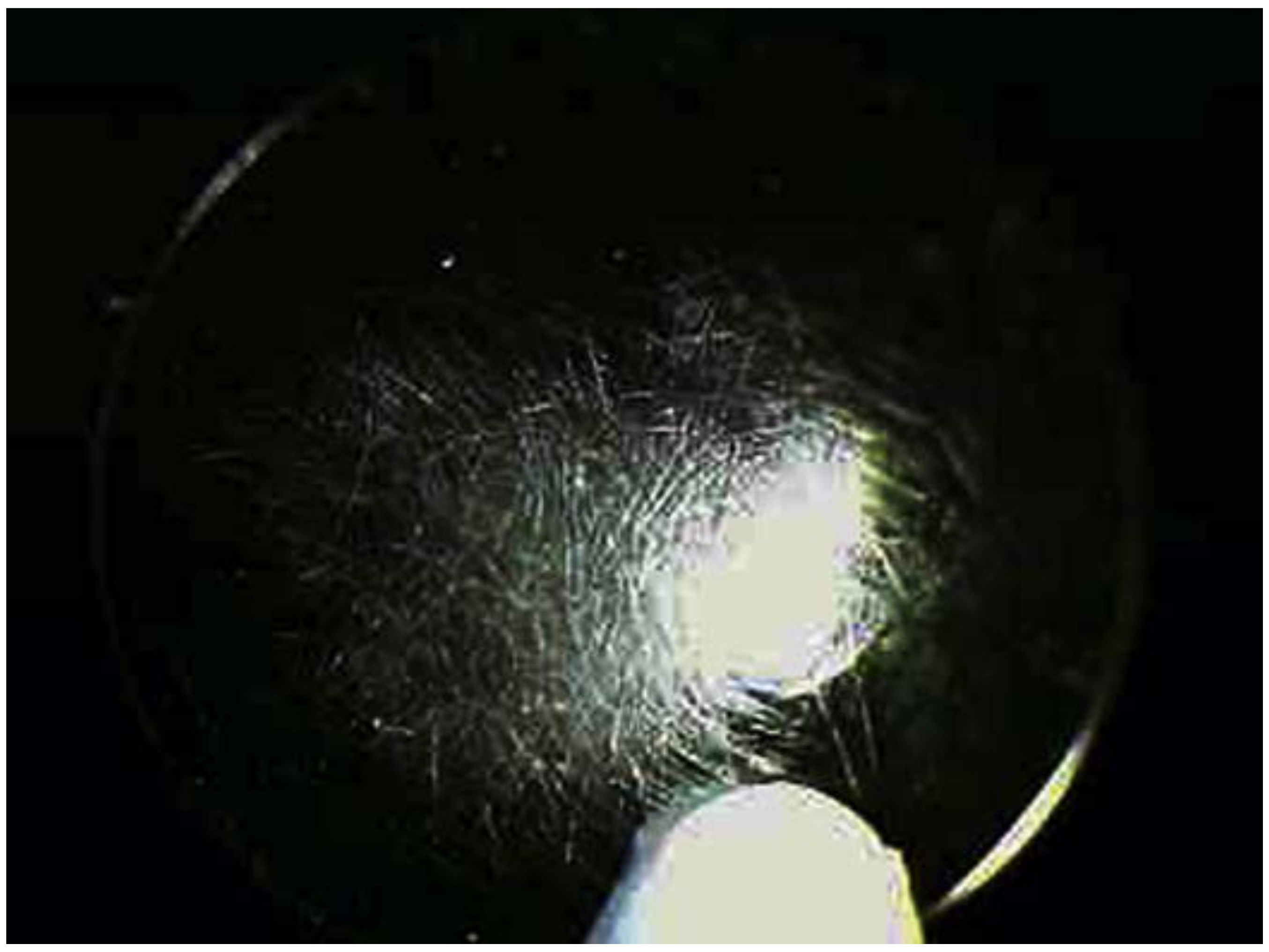

Fig. 20.10 Scratches on the surface of a non-replacement basis rigid lens, seen after lens removal with the lens suspended against a dark background.

DAILY WEAR

For daily-wear basis, planned replacement was shown to reduce the grade for:

- corneal staining within 12 months of commencing the study
- the extent of limbal hyperaemia over time
- the extent of tarsal conjunctival changes over time (Woods and Efron, 1996a).

Regarding the condition of the lenses, planned replacement reduced:

- surface drying within 9 months of commencing the study (Fig. 20.9)
- surface scratching within 9 months of commencing the study (Fig. 20.10)
- mucus coating within 12 months of commencing the study
- surface deposition within 12 months of commencing the study (Woods and Efron, 1996a).

Conventionally worn daily-wear rigid lenses demonstrated a significant reduction in lens thickness over time (Woods and Efron, 1999); this is attributed to the rubbing action causing an erosion of material from the lens centre.

EXTENDED WEAR

For extended wear, planned replacement significantly reduced:

- the grade for corneal staining over time (Woods and Efron, 1996b)
- the grade for conjunctival staining over time (Woods and Efron, 1996b)
- the measured immunoglobulin E levels in the tear film over time (Woods, 1997).

Planned replacement did not prevent a significant increase in tarsal conjunctival changes in the extended-wear group.

Participants not in the planned lens replacement group displayed a significant increase in myopia and a reduction in high-contrast acuity.

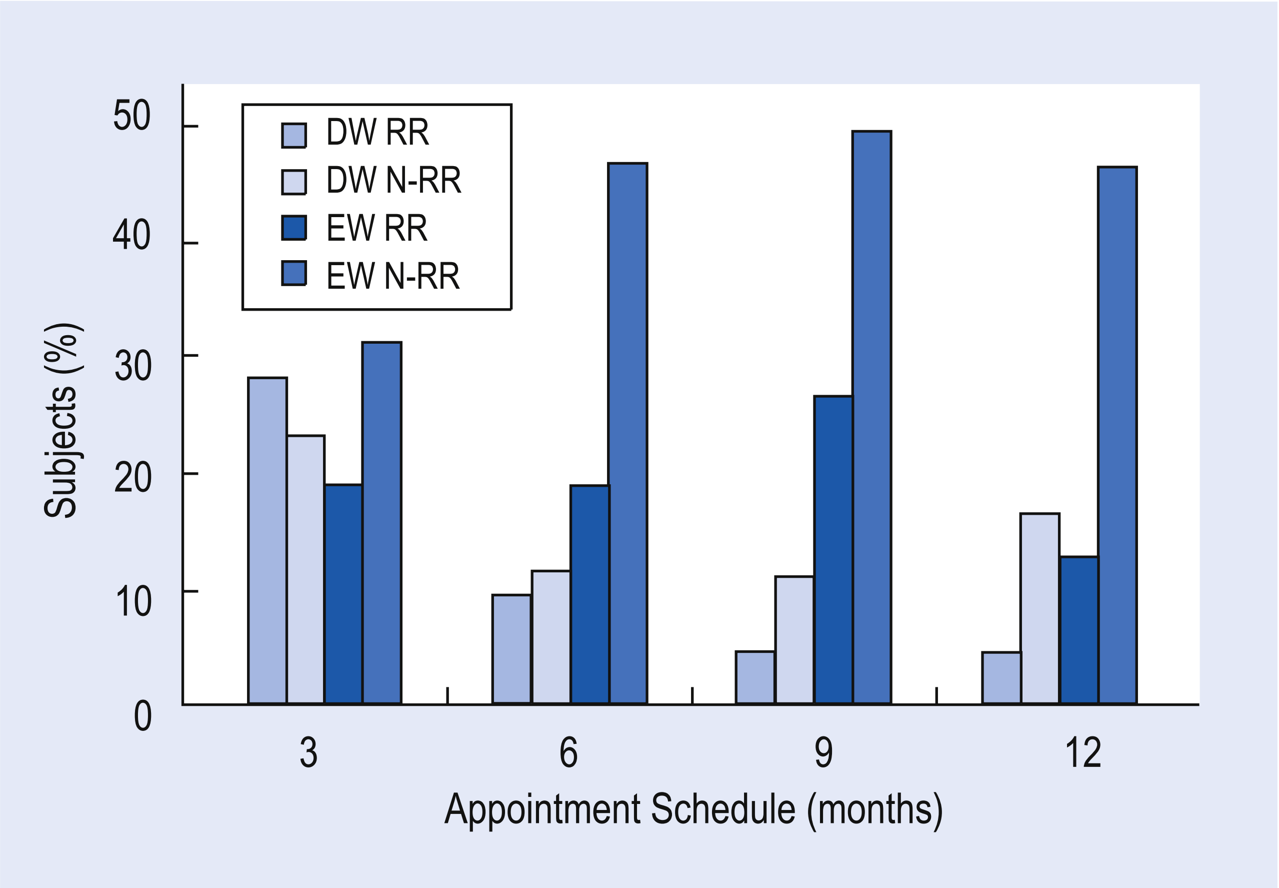

Fig. 20.11 Percentage of subjects reporting lens binding. DW RR = daily-wear regular replacement; DW N-RR = daily-wear non-regular replacement; EW RR = extended-wear regular replacement; EW N-RR = extended-wear non-regular replacement.

Regarding the condition of the lenses, planned replacement reduced the grade for:

- mucus coating over time
- surface scratches over time (Woods and Efron, 1996b).

LENS BINDING

In their studies, Woods and Efron (1996c) observed that lens binding occurred in both the daily-wear groups and the extended-wear groups of wearers. The occurrence of binding was monitored both subjectively and objectively. Subjective binding assessment appeared to be a reliable indicator as to the occurrence of this phenomenon, whereas objective assessment appeared to provide less reliable results. Regular replacement of lenses worn on an extended-wear basis significantly reduced the level of subjectively reported lens binding compared with that reported for the unplanned replacement group. A low incidence of lens binding was shown to occur with daily wear of rigid lenses, irrespective of whether lenses were regularly replaced or not (Fig. 20.11).

Optimum Replacement Schedule

With very little published in the literature to demonstrate the time course of occurrence of adverse events in the eye and lens during rigid contact lens wear (Table 22.1), it is difficult to formulate a clinical criterion for the ideal rigid lens replacement frequency. This criterion can be determined using clinical data, or it can be based on a theoretical model. Both of these approaches are presented below.

CLINICAL DATA

The data of Guillon et al. (1995) suggest that a measurable reduction in surface wettability and increase in surface deposit formation occurs with rigid lenses after 6 months of use. The data of Woods and Efron (1996a, b) suggest that those changes occur after a longer period of wear – that is, clinically significant changes do not appear to occur until after about 9 months. Furthermore, a recommended frequency of replacement should not exceed the life expectancy of any form of rigid lens, which is 9 months. It is reasonable to assume, therefore, that an optimum replacement frequency for rigid lenses would be less than 9 months. In conclusion, therefore, a recommendation to replace rigid lenses every 6 months would seem reasonable, based on the argument that: (1) lenses should be replaced before any adverse ocular or lens surface changes would be expected to occur; and (2) this is an easy-to-remember calendar-based frequency that would facilitate patient and practitioner compliance.

THEORETICAL MODEL

An alternative approach to formulating a recommended replacement frequency for rigid lenses would be to estimate the theoretical ideal replacement schedule using the lifespan and optimum replacement frequency of high-water-content soft lenses as a guide. High-water-content soft lenses have been shown to have an average lifespan of 6 months (Jones, 1990; Jones et al., 1996). The optimum replacement frequency for planned replacement soft lenses could be considered to be between 2 weeks and 3 months (Guillon et al., 1992). A simple ratio of lifespan to optimum replacement frequency could act as a guide to determine how frequently to replace the rigid lenses. Jones et al. (1996) established that the lifespan of rigid lenses made from high-Dk materials is on average 9 months, which is 50% greater than that for high-water-content soft lenses (6 months). The ideal theoretical rigid lens replacement frequency would therefore be 50% more than the range of the optimal soft lens replacement frequencies – that is, between 0.75 and 4.5 months.

Planned Replacement Schemes Available

As is the case with soft contact lenses, manufacturers and practitioners had to be prepared to embrace the concept of planned rigid replacement if this modality was to succeed. Planned replacement of soft lenses required manufacturer-driven schemes to be adopted by practitioners as an accepted standard of practice. Rigid lenses generally are produced by a large number of relatively small prescription or specialist laboratories and it would be unreasonable to expect all of these manufacturers to develop a universal approach to the question of planned rigid lens replacement. As a consequence, manufacturer-driven rigid lens replacement schemes are generally bespoke and provided around their lens warranty arrangements; planned replacement lenses being provided not covered by the warranty agreement are thus at a reduced cost.

Conclusion

The planned replacement of rigid contact lenses has been shown to be clinically beneficial, in terms of maintenance of the integrity of the surface of the contact lens and preservation of ocular health (Woods and Efron, 1996a, b, c). These benefits have been demonstrated to apply to patients wearing rigid lenses on daily- and extended-wear regimens. Based on the limited amount of information available, it is concluded that optimum ocular physiology will be realized by fitting lenses made from high-Dk materials that are designed to be replaced every 6 months. Year-on-year data suggests that practitioners are embracing planned replacement of rigid lenses as they have done for soft lenses.

Access the complete references list online at http://www.expertconsult.com.

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PART 5

Special Lenses and Fitting Considerations

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21

Scleral Lenses

NATHAN EFRON

Introduction

Up until the end of the 20th century, contact lenses manufactured from polymethyl methacrylate or rigid gas permeable materials were fabricated as either corneal lenses (7.0–12.0 mm diameter) or the much larger scleral lenses (>18.0 mm in diameter), with nothing in between. However, it has become apparent over the past decade that there is considerable clinical utility in fabricating rigid lenses with diameters falling within these two extremes; specifically, corneo-scleral lenses (12.1–15.0 mm diameter) and minscleral lenses (15.1–18.0 mm diameter) are being used to manage a variety of refractive and pathological conditions. This chapter considers 'classic' large-diameter scleral lenses; there is considerable overlap in the indications, fitting, handling, maintenance and aftercare between this lens type and the recently introduced, smaller corneo-scleral and miniscleral lenses. Corneal lenses are discussed in Part III and the fitting of corneo-scleral and miniscleral lenses, in the context of correcting keratoconus, are considered in Chapter 26.

Scleral contact lenses are generally perceived as being cumbersome, difficult to fit and problematic. However, rigid gas-permeable (RGP) materials have enabled predictable and straightforward scleral lens fitting methods, creating opportunities for effective, non-surgical visual rehabilitation at all levels of pathology. The uniquely valuable role offers respite from the problems caused by other lens types, or can be the only option when a successful visual outcome is most needed (Picot et al., 2015). The aim of this chapter is not to provide an in-depth coverage of clinical techniques, but rather to give a broad overview, so that the practitioner can be aware of what to expect should a scleral lens wearer seek advice.

To meet a clinical definition of a scleral lens, the diameter must be large enough to have a scleral bearing surface with optic zone clearance extending just beyond the limbus (Fig. 21.1). Assuming a corneal diameter of 12 mm, a minimum annular limbal clearance of 1 mm and a minimum annular scleral bearing surface of 1 mm, the very smallest possible diameter is 16 mm for an eye of normal dimensions. Lenses of less than 16 mm have a role to play, but it is confusing to put them in the category of a scleral lens. At the other end of the range, impression lenses could be greater than 25 mm if necessary, but 23 mm is a more normal diameter for a 'full-diameter' scleral lens.

Advantages and Disadvantages of Scleral Lenses

Contrary to popular belief, the large size and bearing surface provide many positive benefits. Close alignment between the corneal surface and the lens is not necessary; therefore a scleral contact lens can be successful with virtually any corneal topography (Kok and Visser, 1992). They are surprisingly comfortable for the unadapted eye because there is no eyelid–lens edge interaction, foreign bodies behind lenses are not a problem, and there is no localized exposure due to disrupted blinking.

Generally, the end point to the fitting process is well defined and quickly reached, and an extensive power range is possible without excessive mobility. Insertion may be easier for less-dextrous patients, because the lens is not balanced on one finger but rather held between the thumb and a finger. Maintenance is straightforward as dry storage is generally satisfactory even with gas-permeable materials. Polishing or resurfacing is possible.

For a balanced view it is also necessary to appreciate the drawbacks. Production is labour intensive compared with most other lens types. The large size can be intimidating, and there may be a feeling and appearance of excessive bulkiness. Even if skilfully fitted, corneal oxygenation is reduced, and the visual performance is not always as good as with a smaller corneal lens in cases of keratoconus, although Salam et al. (2005) showed that scleral lenses are not necessarily optically inferior to corneal lenses. Decentration in the vertical meridian can cause significant prismatic effects, especially if only one eye is wearing a lens. However, the reason for scleral lens fitting is not usually to enhance the vision compared with corneal lenses, but to provide respite from other problems.

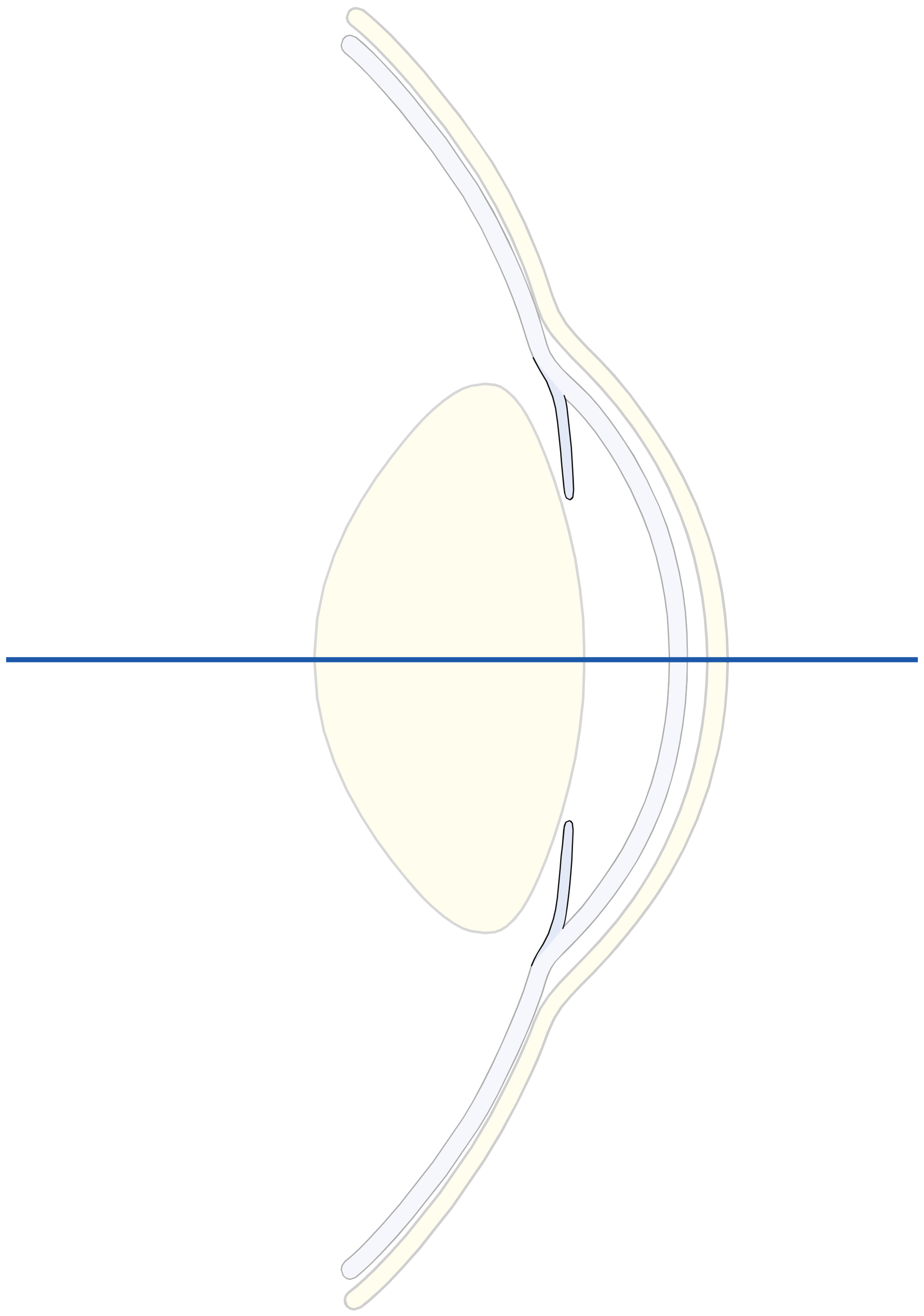

Fig. 21.1 Scleral zone alignment with optic zone clearance extending just beyond the limbus.

Indications for Scleral Lenses

To assess the extent of scleral lenses around the world, Efron et al. (2011) analysed data relating to 105 734 contact lens fits (137 infants, 1672 children, 12 117 teenagers and 91 808 adults [age ≥18 years]). Scleral lenses were fitted to a considerably greater number of infants (0.7% of all fits), compared with children (0.1%), teenagers (0.2%) and adults (0.2%); these differences were statistically significant ($\chi^2 = 3.0$, $p = 0.4$). An international survey of 23 000 fits in 34 countries in 2015 revealed that scleral lenses accounted for approximately 8% of all rigid lens fits (Morgan et al., 2016).

Visser et al. (2007a) have reported that the primary indications for scleral lens fitting today are keratoconus (50%) followed by post-penetrating keratoplasty (20%), lesser indications being irregular astigmatism, keratitis sicca, corneal dystrophy, and multiple diagnoses. The finding of Efron et al. (2011) of very low levels of scleral lens fitting to minors and adults highlights the highly specialized but vital role that such lenses have in the clinical management of rare ocular abnormalities in minors as well as adults.

Provided there is a sound underlying indication for contact lens management, scleral lenses are indicated when they can be applied to beneficial effect (Schein et al., 1990; Visser, 1990; Kok and Visser, 1992; Foss et al., 1994; Pullum et al., 2005; Pullum and Buckley, 2007; Jacobs, 2008). The main indication is optical correction of an irregular corneal surface (Visser et al., 2007a).

An analysis of 888 consecutive patients (1353 eyes) who were continuing scleral lens wear at their most recent aftercare appointment was carried out at a dedicated clinic at Moorfields Eye Hospital, London; the percentages for each indication are shown in Fig. 21.2. A total of 61.6% (824 eyes) were for keratoconus or other primary corneal ectasia (PCE), and 20.5% (274 eyes) were for corneal transplant, most of which were keratoconus indicated. Retention of a precorneal fluid reservoir for various ocular surface disorders constituted 10.7% (143 eyes), high myopia or aphakia combined 4.1% (55 eyes) and ptosis props 1.3% (18 eyes).

Ocular surface disorders where scleral lenses might be beneficial include Terrien's marginal degeneration (Cotter and Rosenthal, 1998), Stevens–Johnson syndrome (Fine et al., 2003), pellucid marginal degeneration (Looi et al., 2002), ocular cicatricial pemphigoid, persistent corneal epithelial defects (Rosenthal et al., 2000) and moderate to severe dry eye (Alipour et al., 2012). Their use may reduce the rate of epithelial defect recurrence in stem-cell-deficient and neurotrophic corneas (Rosenthal and Cotter, 2003). Margolis et al. (2007) have also reported on their use in advanced atopic keratoconjunctivitis.

Moderate ametropia rarely warrants scleral lens fitting as first choice, but should be considered if there are intractable problems with corneal or hydrogel lenses. There is an indication for recreational or occupational reasons when extra stability is required, sometimes for water sports, or to cater for dusty environments. Many people were issued with scleral lenses before the use of corneal and hydrogel lenses became widespread: they are mostly elderly, but some have every intention of continuing lens wear. They may not be receptive to refitting with corneal or hydrogel lenses, nor do they need to be if any sequelae do not represent a threat to their vision for the duration of their expected lifespan.

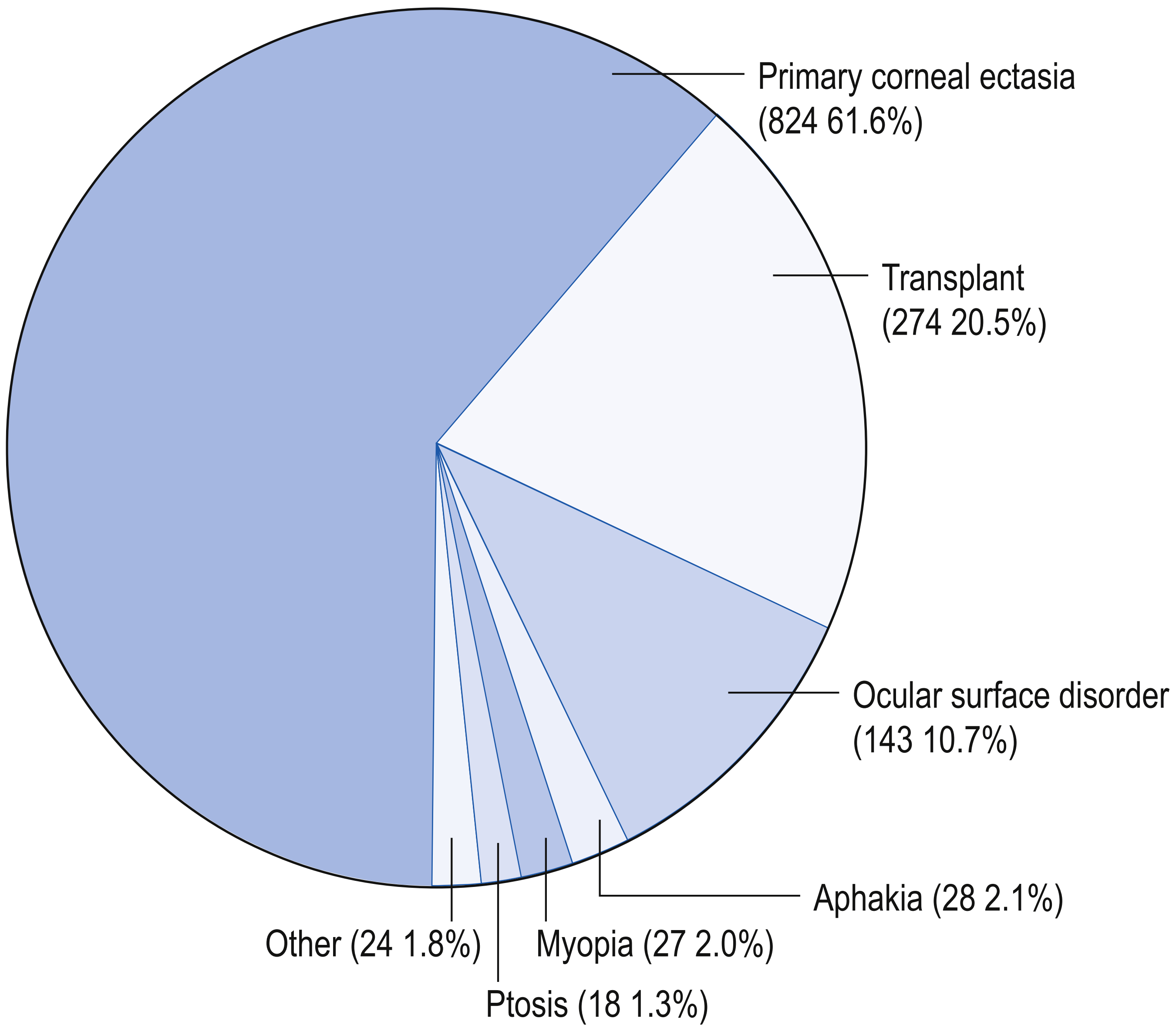

Fig. 21.2 Indications for contact lens management of patients attending Moorfields Eye Hospital 2000–2007. A total of 888 patients (1353 eyes) were studied.

Fitting Principles

Initially scleral lenses were made from glass (from 1888 until the 1940s), then polymethyl methacrylate (PMMA); however, the introduction of RGP materials brought renewed interest in the fitting of scleral lenses (Ezekiel, 1983; Ruben and Benjamin, 1985; Pullum 1987; Lyons et al., 1989; Schein et al., 1990). Scleral lenses can be fitted either from preformed sets or by impression moulding.

NON-VENTILATED PREFORMED SCLERAL LENSES

The term 'sealed' has been widely used to describe a lens without a fenestration. However, the same word can also mean there is no or minimal tear exchange under the scleral zone, or that the lens retains an air-free precorneal fluid reservoir. There may be a significant tear exchange or even admission of air bubbles into the precorneal fluid reservoir via unintentional scleral zone channels if a non-fenestrated lens is imperfectly aligned with the sclera. To clarify for the remainder of this chapter, 'non-ventilated' rather than 'sealed' is used to describe a lens designed with no intentional means of tear exchange, such as a fenestration.

The increased corneal oxygenation available with RGP materials avoids the need for fenestrations (Pullum et al., 1990, 1991; Pullum and Stapleton, 1997), thereby reducing the problem of air bubbles admitted to the precorneal fluid reservoir. The reservoir acts as an effective cushion, therefore settling on the globe is reduced and the effect is more predictable, giving increased latitude reaching an end point in the fitting process. Consequently, many more eyes can be fitted with coaxial preformed designs than was ever possible with PMMA (Ramero-Rangel et al., 2000).

A detailed description of the fitting process is beyond the scope of this chapter, but it is appropriate to outline the principles. More in-depth accounts can be found in two recent texts (Pullum, 2005, 2007).

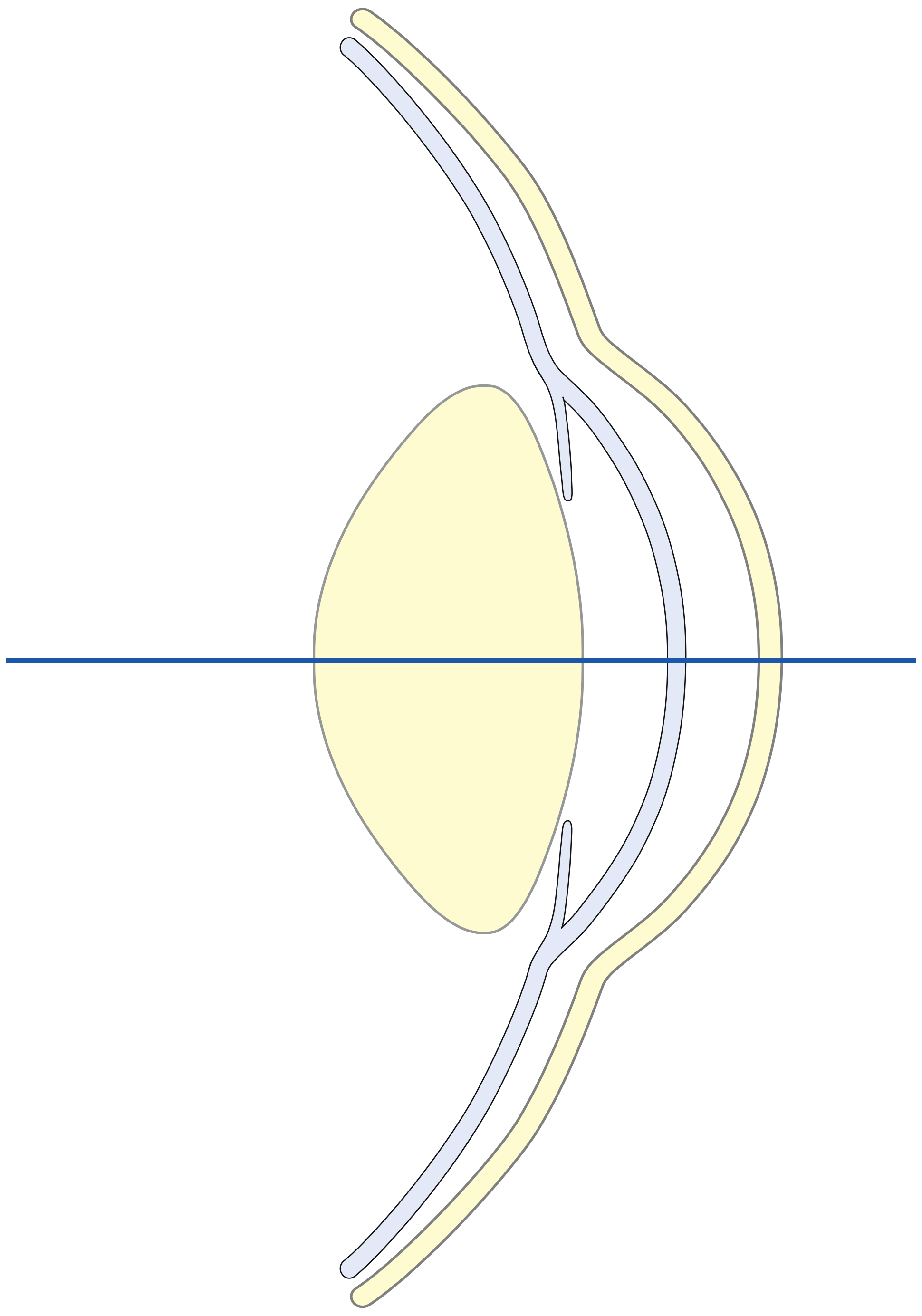

Fig. 21.3 Steep scleral zone causing vaulting and increased optic zone clearance with an unchanged back optic zone radius.

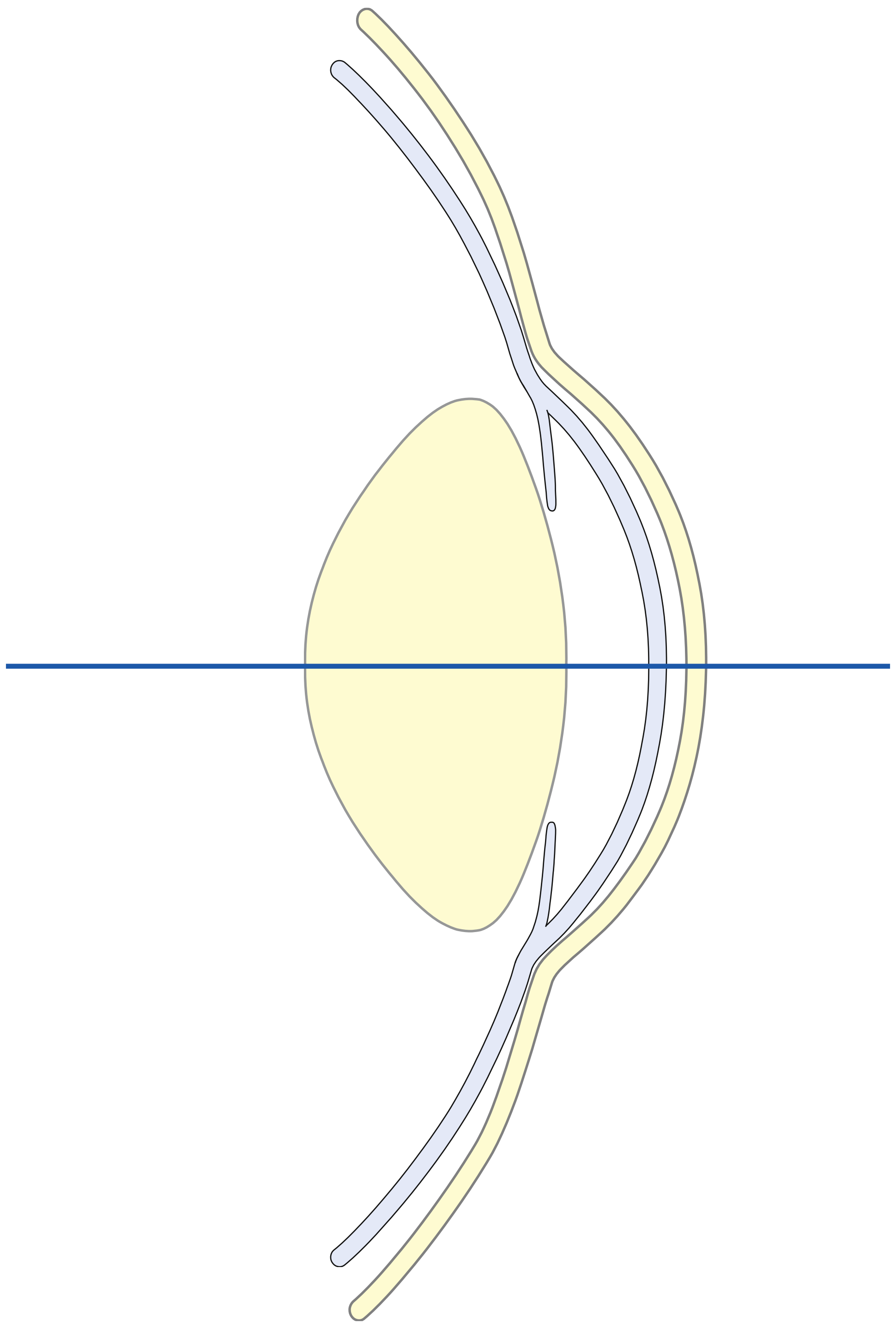

Fig. 21.5 Flat scleral zone with a reduced annular scleral bearing surface just outside the limbus, but no change to the apical clearance.

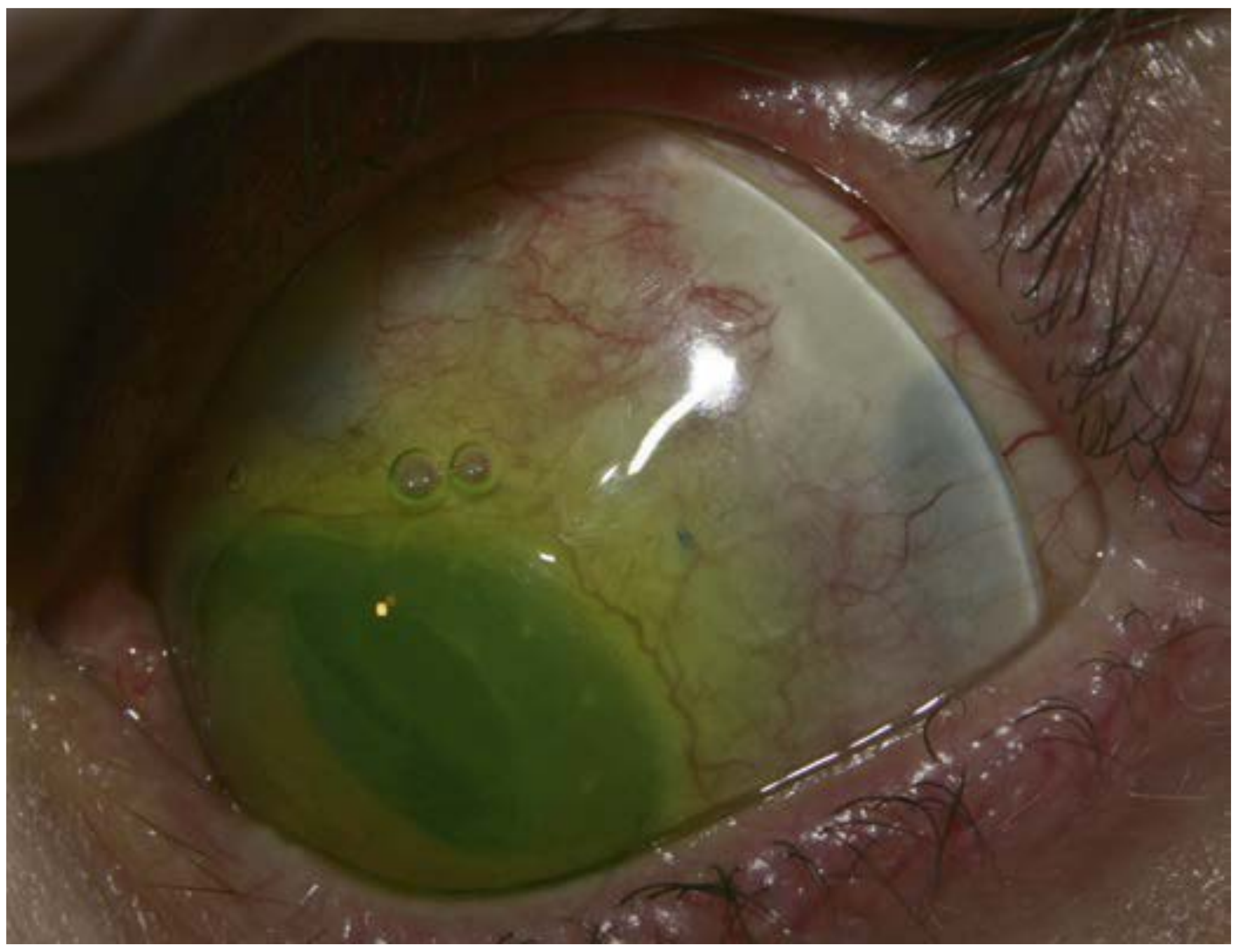

Fig. 21.4 Preformed rigid gas-permeable scleral in situ illustrating a steep scleral zone. Fluorescein is seen extending beyond the limbus, although not excessively. However, the peripheral conjunctival blood vessels beneath the lens are occluded, giving a blanched appearance. The pathology is corneal transplant that has been complicated by secondary glaucoma. A bleb just above the limbus is visible. Although somewhat steep on the sclera, this was deemed preferable to changing to a flatter fitting, which could compress more on the bleb following any settling back.

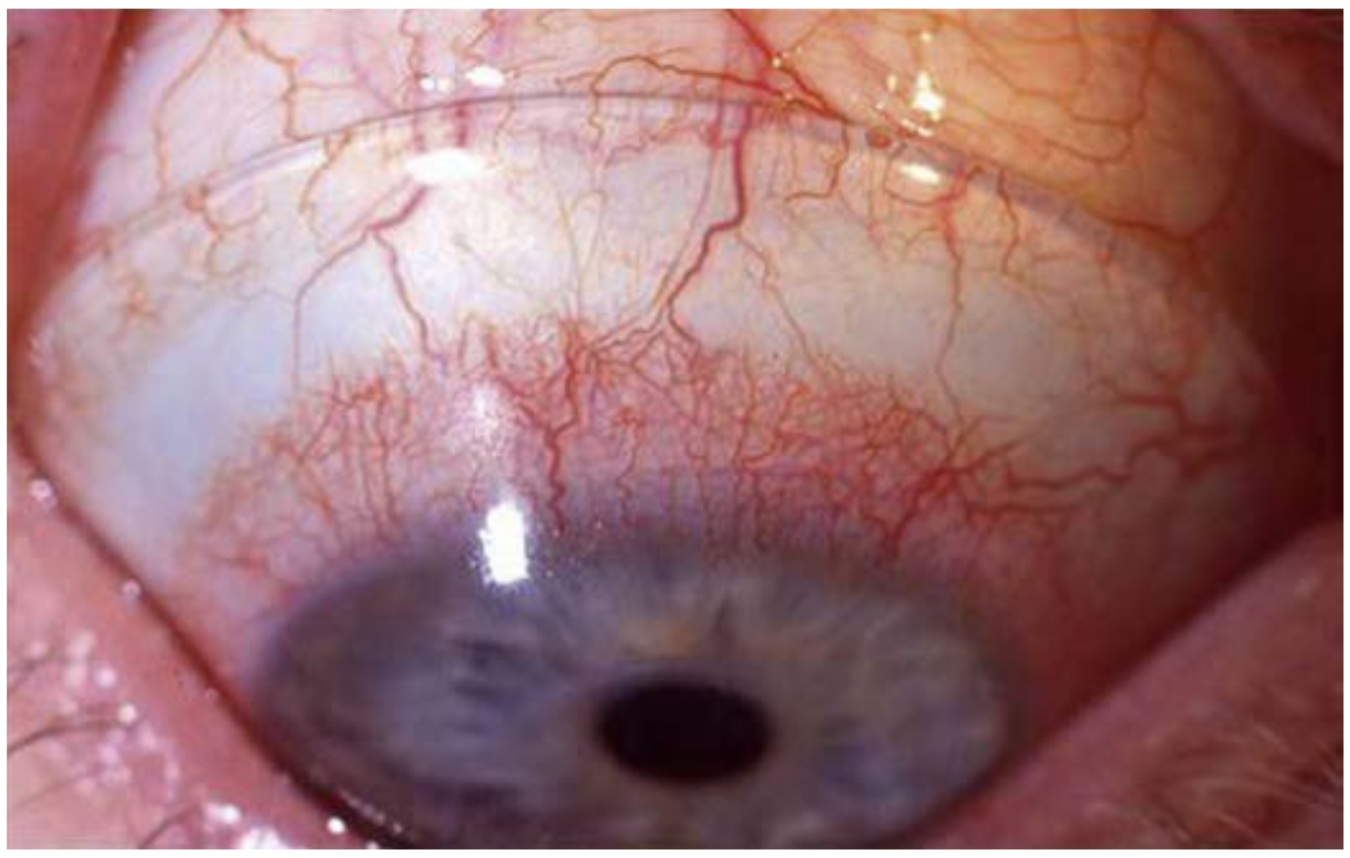

Fig. 21.6 Preformed rigid gas-permeable scleral in situ illustrating a flat scleral zone. Conjunctival vessel blanching is clearly seen in the mid-periphery. The annular scleral compression zone causes a marked unsightly congestion between the blanched region and the limbus, which may lead to an increased risk of corneal vascularization in a predisposed eye.

THE SCLERAL ZONE

The objective in non-ventilated RGP scleral lens fitting is to achieve corneal clearance extending far enough into the scleral zone to avoid compression of the limbus with optimum scleral alignment over the broadest possible area, as previously shown in Fig. 21.1. Perfect alignment to the sclera is not crucial, nor is it possible, as it is not conveniently spherical or symmetrical about its axis. There should be minimal occlusion of the conjunctival blood vessels, but sufficient sealing on the sclera to prevent introduction of air bubbles into the precorneal fluid reservoir.

The back optic zone radius (BOZR), back optic zone diameter (BOZD) and back scleral radius (BSR) influence the optic zone clearance. If the BSR is too steep, the lens may vault the whole anterior eye from its periphery, occluding the peripheral conjunctival vessels if excessive, as illustrated in Figs. 21.3 and 21.4.

If the BSR is too flat, the scleral zone stands off the globe, and may occlude the mid-peripheral conjunctival vessels, as seen in Figs. 21.5 and 21.6.

The back scleral size (BSS) has a less predictable impact. A larger-diameter lens may impinge on peripheral scleral nodules (e.g. the medial and lateral recti muscle insertion points). If so, the lens vaults from the periphery, giving a similar appearance to that with a steep BSR. The optic should be displaced 1–1.5 mm if the diameter is greater than 20 mm. This reduces the width of the nasal scleral zone, improving centration and preventing the edge impinging on the inner canthus on nasal gaze movements.

OPTIC ZONE SAGITTAL DEPTH AND OPTIC ZONE PROJECTION

The optic zone sagittal depth (OZS), and hence the corneal clearance, is determined by varying the BOZR and BOZD in combination. Modern designs blend the optic zone–scleral zone junction so that it is barely perceptible, or include an aspheric transition zone. The primary BOZD remains at the junction between the continuation of the BOZR and the BSR. Alternatively, progressive increments in the projection of the optic zone (OZP) from the extrapolation of the BSR, but without reference to the BOZR or BOZD, can be used to determine the optimum apical clearance (Fig. 21.7).

For an indication of the OZP scale, the range for most normal corneas is 1.0–2.0 mm compared with a rare highly globic corneal profile, which may require up to 5.0 mm (Fig. 21.8). Fig. 21.9 shows a non-ventilated RGP scleral lens in situ with a glancing contact on the same eye. Even an eye with such a protrusive corneal profile is quite often straightforward when fitting a non-ventilated RGP scleral lens.

Between 0.20 and 0.30 mm is a suitable OZS or OZP increment for non-ventilated lenses, and 0.25 ± 0.1 mm an optimal apical clearance. Pachymetry is not necessary as the depth of the precorneal fluid reservoir is estimated accurately enough in comparison with the corneal thickness; 0.25 mm is considerably greater than a typical clearance for a fenestrated lens, where anything over 0.1 mm at the apex would admit air bubbles crossing the visual axis. Fig. 21.10 shows an eye with moderate keratoconus. The same eye is fitted with scleral lenses to illustrate corneal contact (Fig. 21.11A), the effect of an OZP increment of 0.25 mm giving glancing contact (Fig. 21.11B), and the effect of an OZP increment of a further 0.25 mm giving corneal clearance (Fig. 21.11C).

If air bubbles do become trapped in the precorneal fluid reservoir, refitting a lens with reduced apical clearance, if there is scope, tends to shift the bubbles towards the periphery. Fitting with a flatter BSR may improve scleral zone sealing by moving the bearing surface closer to the limbus, which is the most symmetrical region of the sclera. Reducing the diameter may have the same effect. If still unsuccessful, an eye impression may be necessary to improve alignment on the sclera.

NON-COAXIAL SCLERAL LENSES

Toroidal Lenses

If a non-ventilated coaxial RGP lens is impossible to fit because the sclera is insufficiently symmetrical, toroidal scleral zone designs and impression RGP lenses are available (see below). The fitting objectives are similar to those for non-ventilated coaxial lenses – that is, optimal scleral zone alignment and a precorneal fluid reservoir extending 1–2 mm beyond the limbus. A toroidal design remains an approximation to the scleral topography but may be a closer match to typical scleral contours than a coaxial design, hence may improve centration and sealing on the sclera. Toric scleral lenses have been shown to return rapidly to their original position after rotation (Visser et al., 2006). Wearing time, comfort, visual quality and overall satisfaction may be improved when back-surface toric designs are used, compared with spherical ones (Visser et al., 2007b).

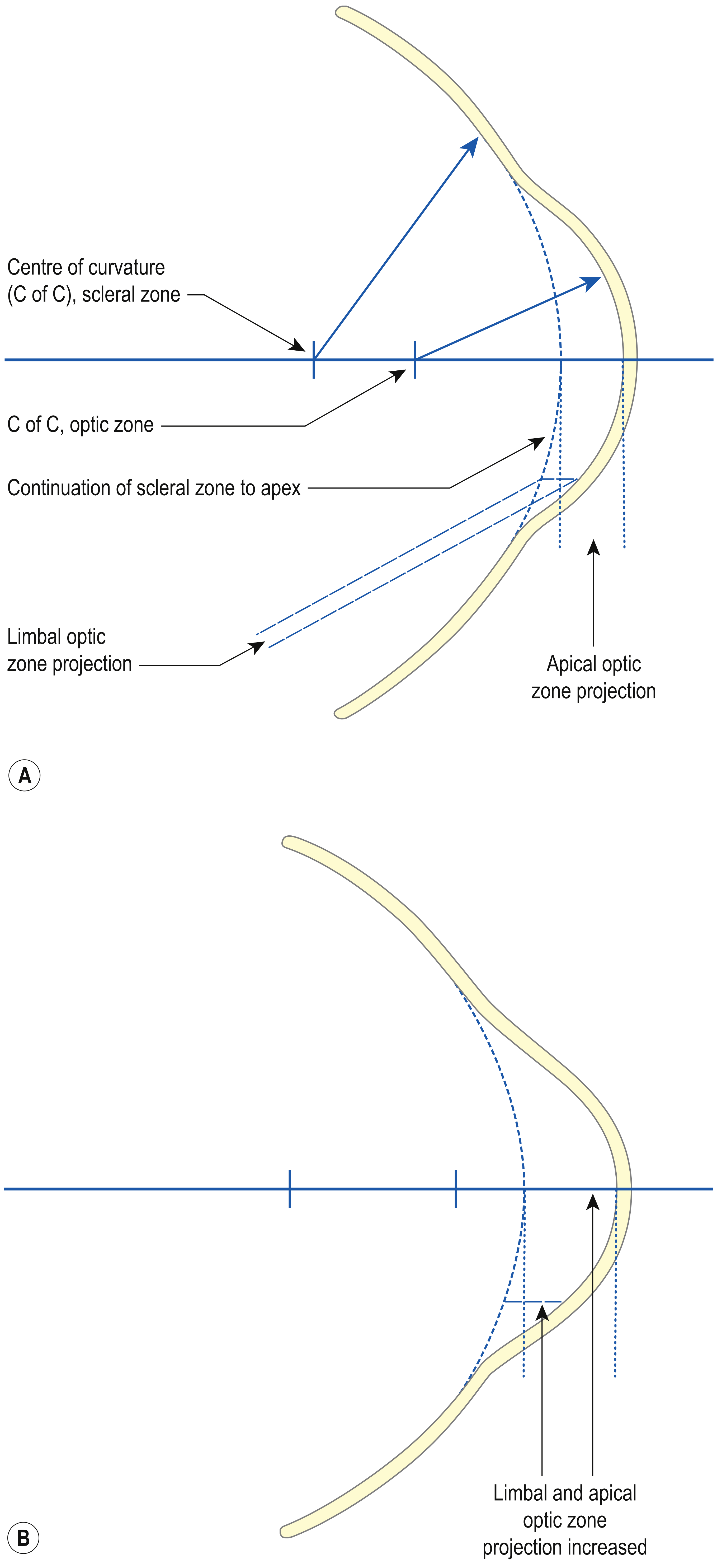

Fig. 21.7 (A) Optic zone projection (OZP). (B) Increased apical and limbal OZP.

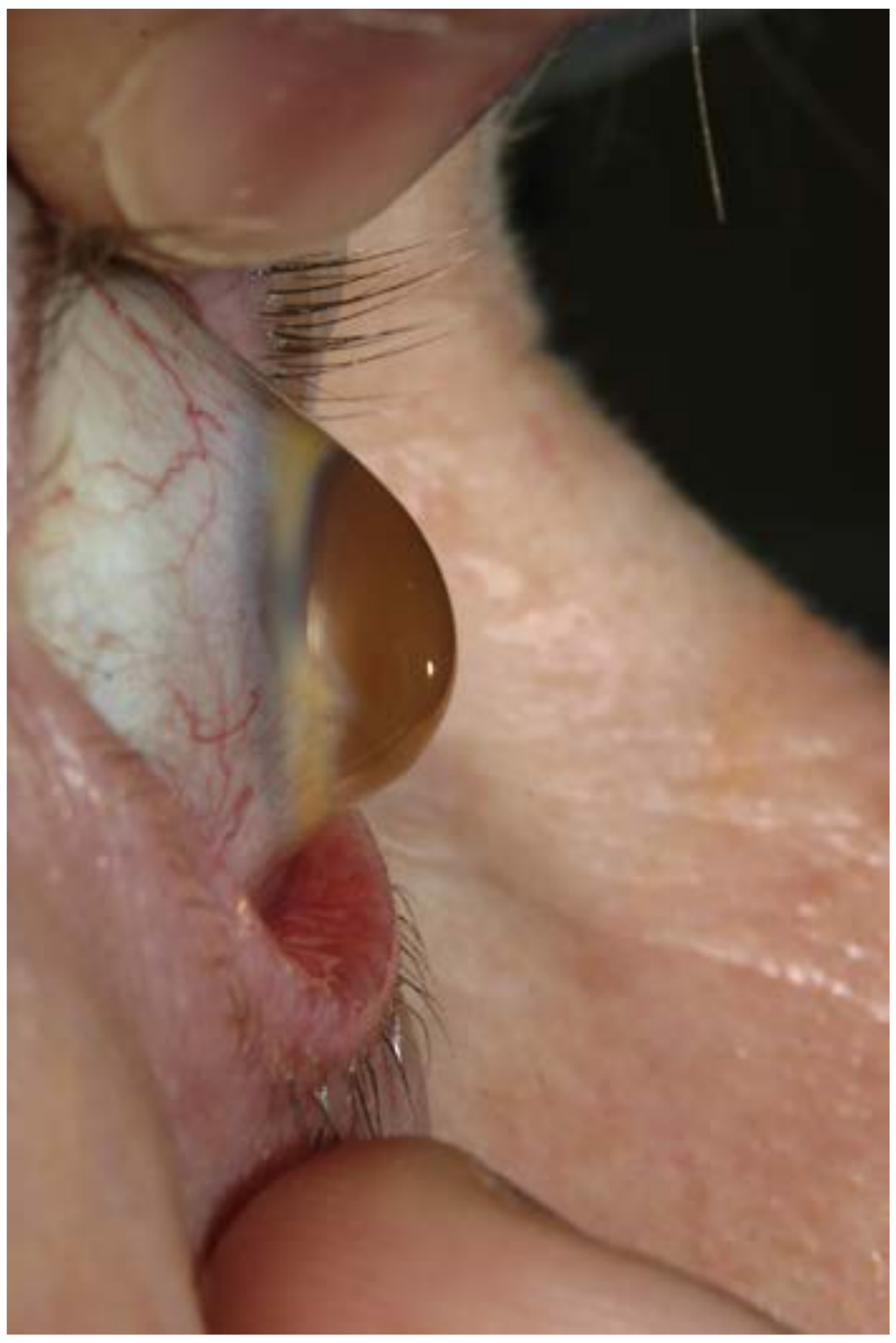

Fig. 21.8 Spectacular, but rare, keratoglobus. This case was also diagnosed as Terrien's marginal degeneration, typified by circumferential opacification at the limbus, but the impact on the visual function and the management options are the same irrespective of the name given to the condition.

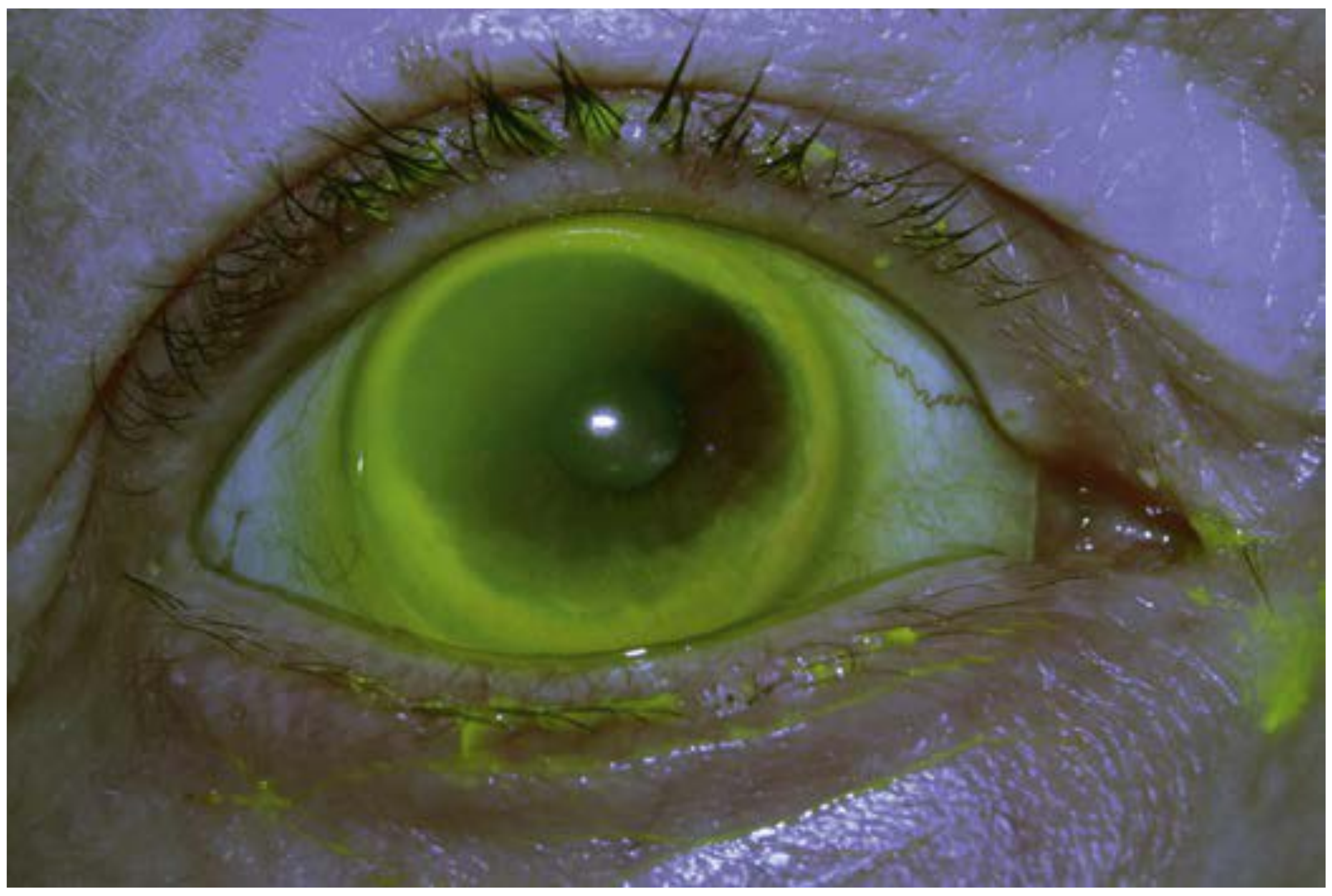

Fig. 21.9 Preformed rigid gas-permeable scleral lens in situ on the same eye as shown in Fig. 21.8, illustrating a glancing apical contact zone but limbal clearance.

Impression Moulding

An impression lens has by definition the best possible alignment, but requires development of different skills on the part of both the clinician and the manufacturer (Pullum, 1987; Lyons et al., 1989; Pullum et al., 1989). Unlike with PMMA, an RGP scleral lens cannot be produced by heat moulding as the materials are not thermoplastic, but an optimally fitting PMMA lens can be duplicated in an RGP material.

Fenestrated Lenses

A means of ventilation is a prerequisite for a PMMA scleral lens to facilitate some tear exchange. Most commonly this is done with a fenestration; however, slots, truncations and channels have also been used (Pullum and Trodd, 1984). Compared with fitting a non-ventilated lens, fenestrated scleral lens fitting represents a major undertaking, but there are indications for trying – for example, if there are intractable difficulties inserting a non-ventilated lens air free. Some fenestrated PMMA scleral lenses are used by established wearers and some are still being issued for new cases. If there is a satisfactory wearing schedule, and acceptable sequelae, the best option may be to leave well alone. If unacceptable, an RGP scleral lens could be offered, either by refitting a non-ventilated design or, if necessary, by duplicating the existing shape. However, the wearer may have had the same lens for many years, and could have a distinct preference for his/her 'old friend'. In particular, a corneal contact zone with a PMMA lens that has been well tolerated could be less comfortable if the original shape is duplicated in an RGP material, probably because of the increased coefficient of surface friction with RGP materials.

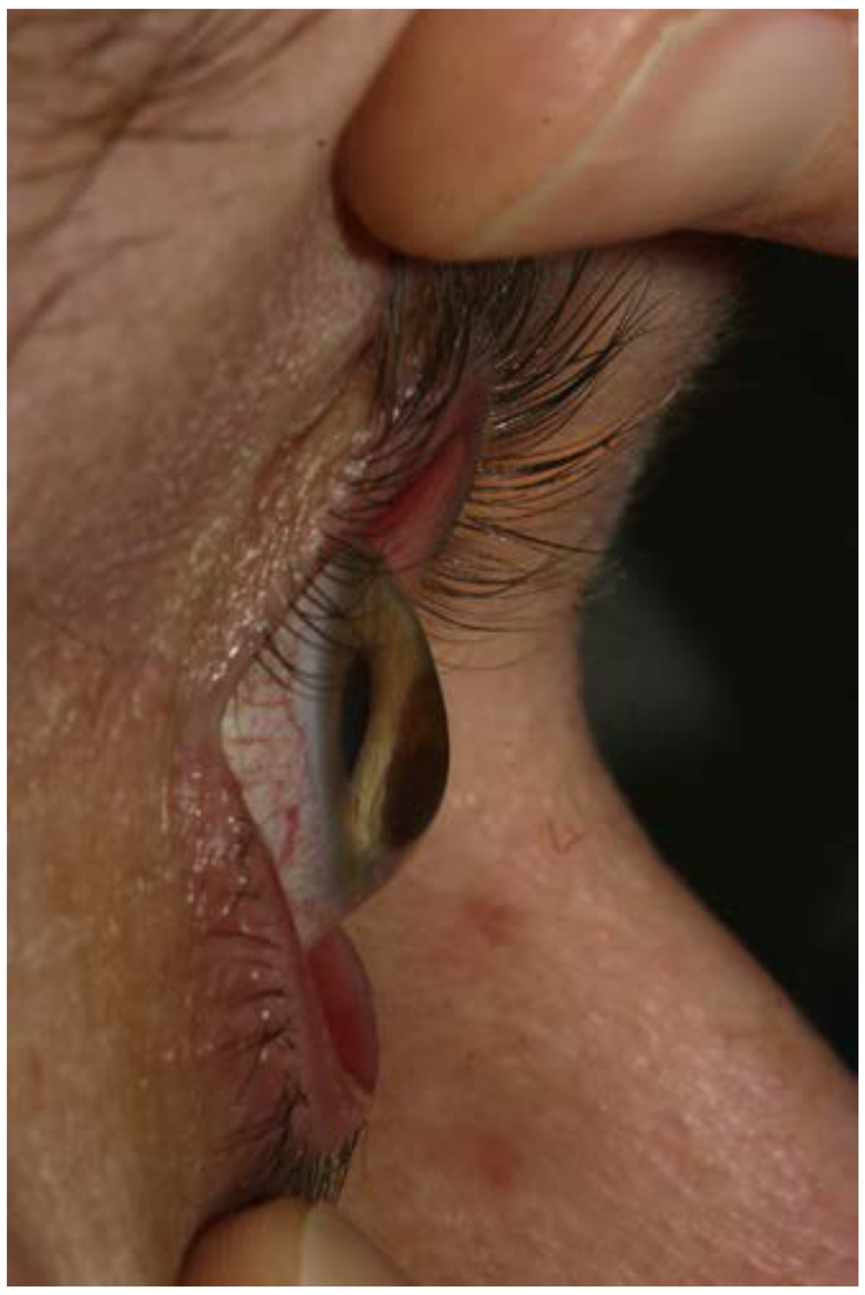

Fig. 21.10 Moderately advanced keratoconus with a downwardly decentred apex.

Bubbles trapped in the precorneal fluid reservoir are almost unavoidable with fenestrated lenses, hence the fit of the lens is in part determined by their appearance. If the bubble crosses the visual axis, the vision is disrupted. A crescent-shaped bubble extending approximately one-third of the corneal diameter, but restricted to the limbus, is considered optimal (Fig. 21.12).

If the lens settles back on the globe, which it usually does, the apical clearance is reduced. If initially there was optimal clearance, just avoiding a bubble, after a few minutes there may be an unacceptable contact zone. If the corneal topography is not regular, which is the case in the majority of cases needing scleral lenses, the depth of the precorneal fluid reservoir is not uniform. The lens therefore fits too close in places as well as there being bubbles in the precorneal fluid reservoir. An impression at the starting point helps to reduce these problems as the scleral-bearing surface is maximized, and the optic zone is fabricated according to the individual topography.

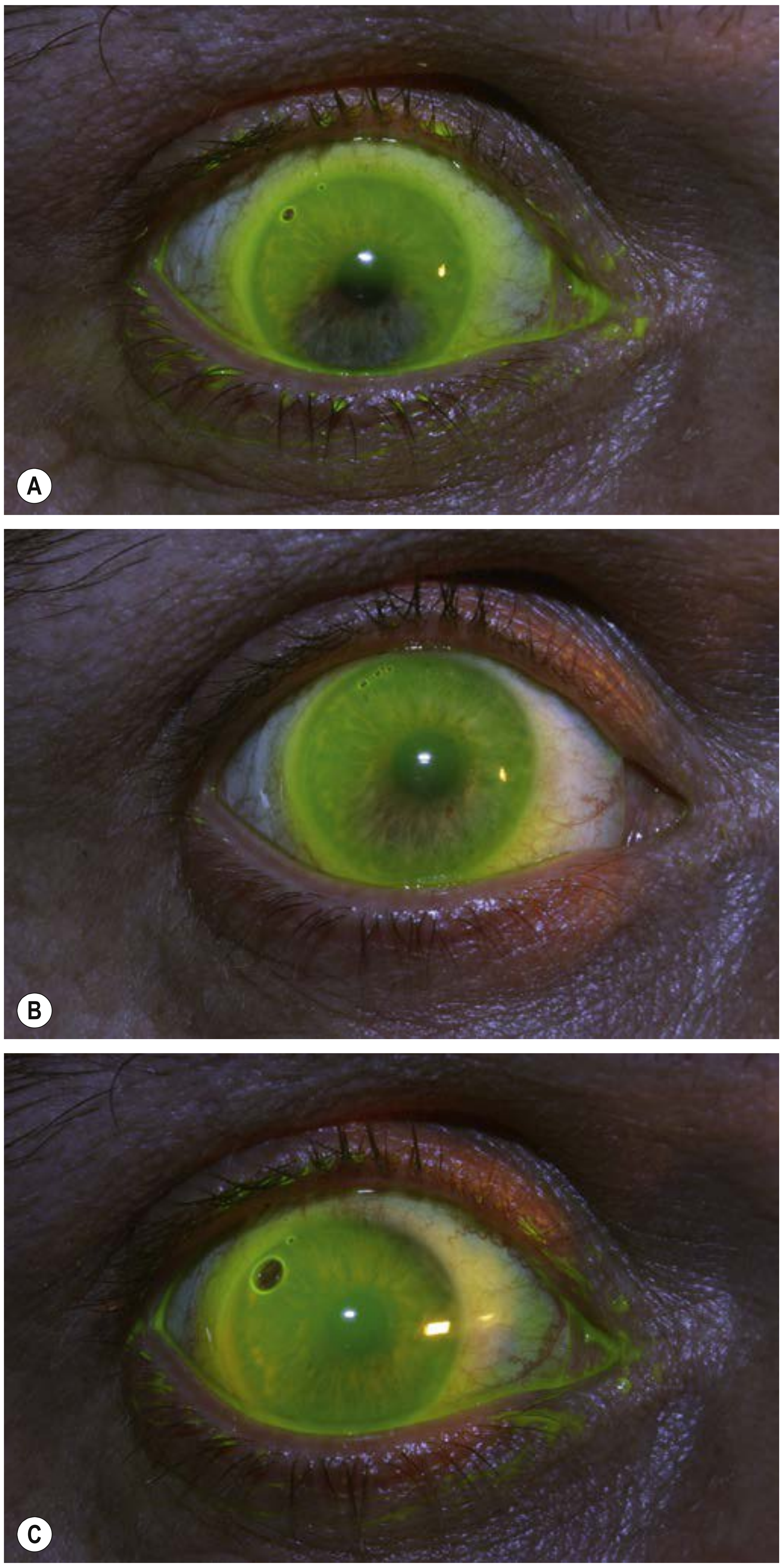

Fig. 21.11 Preformed rigid gas-permeable scleral lenses in situ on the same eye as shown in Fig. 21.10. (A) The apical contact could be described as compressive. (B) Lens with an apical optic zone progression increment of 0.25 mm to give glancing contact. (C) Lens with an apical optic zone progression increment of 0.5 mm to give corneal clearance.

Modification

It is likely that a currently worn fenestrated PMMA lens was originally fitted from an eye impression. The practitioner should never attempt to modify an existing impression lens but rather should make adjustments to a new shell pressed over a dental stone cast of the original lens. Alternatively, another eye impression should be taken to start again from the beginning. Modification of an RGP scleral lens, other than a power change carried out by a competent laboratory, should not be attempted as the outcome is far from predictable, and it is impossible to restore a lens to its original condition.

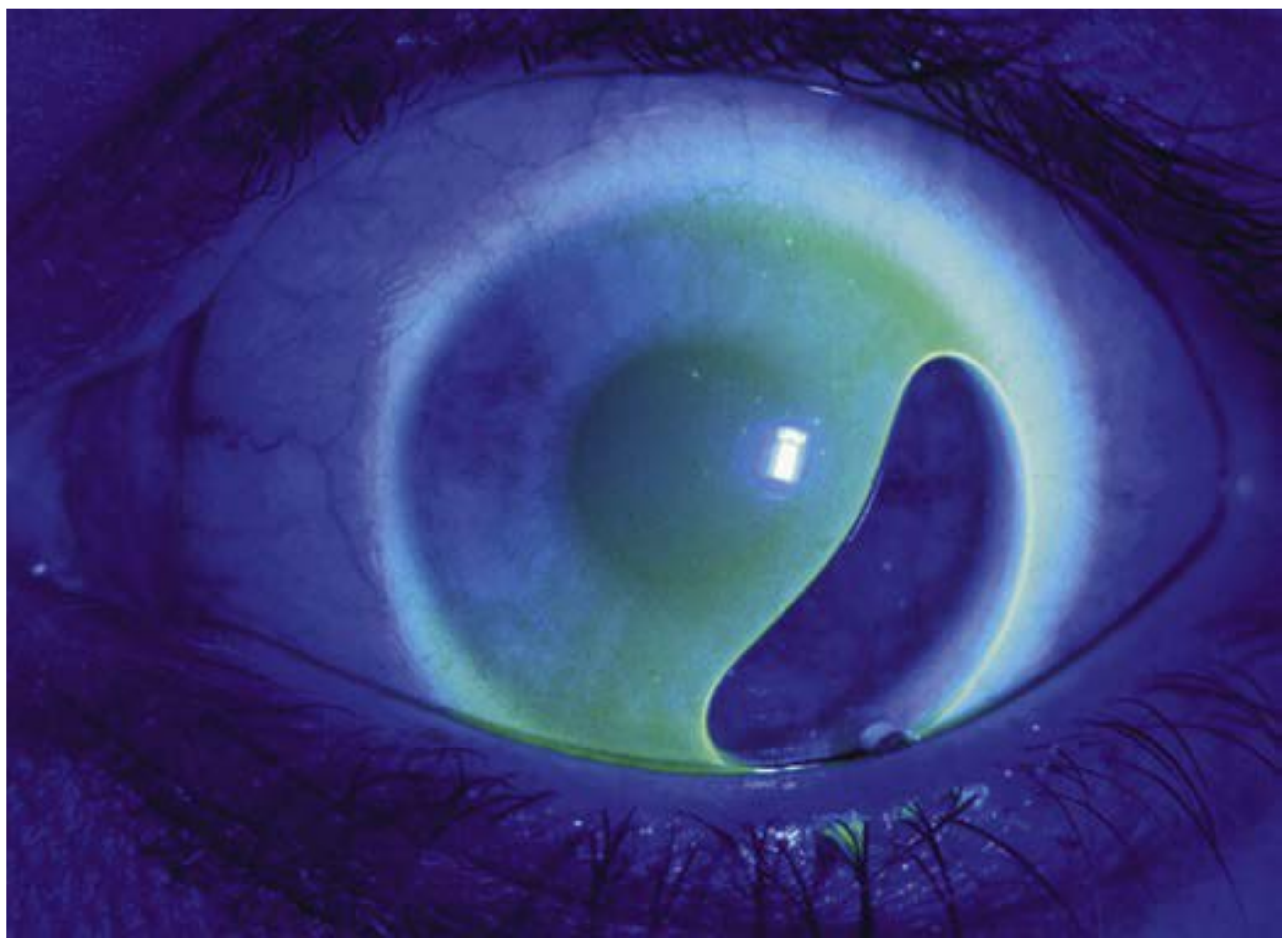

Fig. 21.12 Typical shape and size of bubble beneath a fenestrated scleral lens.

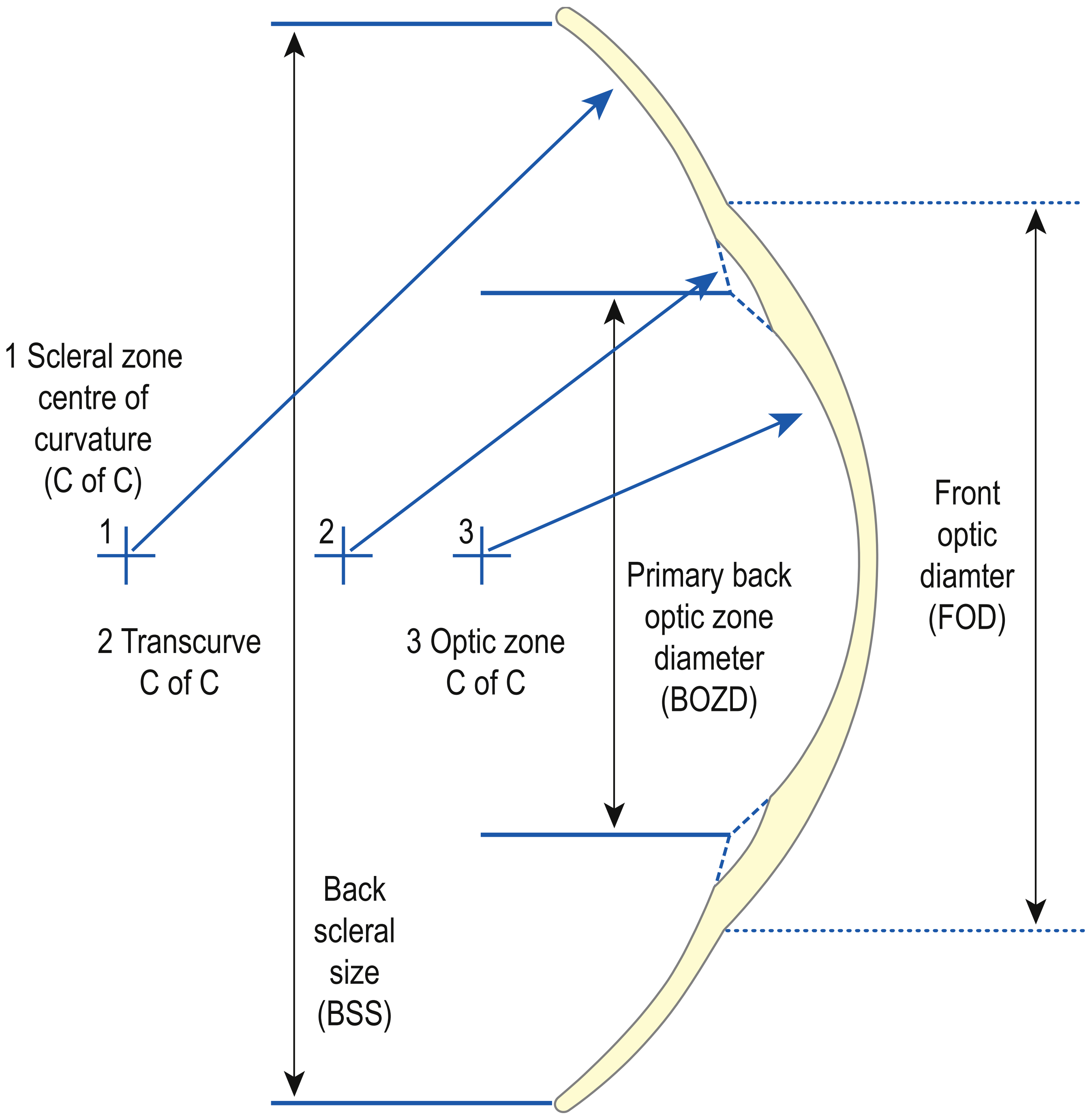
1 Scleral zone centre of curvature (C of C)
1
2
3
2 Transcurve C of C
3 Optic zone C of C
Primary back optic zone diameter (BOZD)
Front optic diamter (FOD)
Back scleral size (BSS)

Fig. 21.13 Preformed scleral lens parameters.

Ordering Scleral Lenses

For a preformed scleral lens of 'traditional' style, the practitioner should specify the BOZR, the primary BOZD, the BSR, the optic zone displacement (D) in mm, the BSS, which is independent of the thickness, and the BVP. A transition curve to blend the optic–scleral junction is usually required, but the manufacturer should be left to select the optimum design. Fig. 21.13 illustrates the parameters of a scleral lens. Wide-angle lenses are probably the most widely used integrated scleral zone/optic zone lenses and have been available, unchanged from their original design, for over 60 years. The BOZD is a function of the BOZR and the BSR, so specification requires just the BOZR, BSR, BSS, D and BVP.

For non-ventilated RGP scleral lenses, it has become more usual for manufacturers to have their own ordering system, which should be followed to avoid errors. Usually, this entails stating the optimum lens used from the diagnostic fitting set, and details of the overrefraction, with any departures from the trial set parameters described.

A cast of an impression or preferably a cast from which a moulded lens can be made can be sent to a competent laboratory. The BSS can be indicated by drawing a line on the cast. If the requirement is for a PMMA lens, the manufacturer should be given full freedom to produce the back surface. The optic zone is fabricated by grinding diamond-coated spherical stones on to the back surface of the shell, the optimum reached by a skilled trial-and-error process. A power formula must be provided – that is, the result of a refraction over a scleral lens or a limbal diameter corneal lens of known BOZR and BVP. The manufacturer can then make the appropriate power allowance for the difference between that BOZR and that of the final lens. For a non-ventilated impression RGP lens, a specialist manufacturer would need a fitted PMMA shell or a cast of the shell in order to duplicate the lens in an RGP material.

Lens Hygiene and Maintenance

STORAGE

Dry storage is normal for PMMA scleral lenses and is also satisfactory for RGP sclerals. Wet storage may enhance surface wetting in some cases, in which case hydrogel lens multifunctional solutions are preferable to the more viscous rigid lens soaking solutions.

CLEANING AND CONDITIONING

There being very little tear exchange with non-ventilated RGP scleral lenses, viscous solutions to condition the back surface remain in contact with the cornea for long periods and they may lead to accumulative sensitivity to the preservatives. A non-preserved cleaner, rather than a conditioning solution, which is rinsed off with non-preserved saline prior to insertion, may be preferable.

SALINE FOR FILLING NON-VENTILATED RGP SCLERAL LENSES

Non-preserved saline is necessary for filling non-ventilated RGP scleral lenses prior to insertion, because the solution is retained in contact with the cornea for the duration of wear. Some wearers become sensitive to multidose saline, in which case preservative-free unit dose preparations are necessary. Aerosol saline tends to be too gassy for this application.

REWETTING

If lenses need refreshing during the day, soft lens multipurpose solutions may be beneficial. The cleaning action is not as powerful as dedicated cleaners, but rinsing from the surface prior to reinsertion is a quick process compared with the use of a cleaning agent.

Problems and Complications with Scleral Lens Wear

Walker et al. (2016) have reviewed the recent literature in relation to complications of current generation scleral lenses. They found reports of infection with the scleral devices, although these are often seen in severely compromised corneas. Hypoxic and inflammatory complications are rarely reported in the literature. The somewhat complex relationship of a scleral lens on the eye can create fitting and removal challenges. Anomalies such as conjunctival prolapse, epithelial bogging, midday fogging, and limbal bearing have been reported, and appear to be unique sequelae to scleral lens wear. Walker et al. (2016) concluded that, although modern scleral lens technology has broadened the scope in which practitioners can treat patients with irregular ocular surfaces, reports of these complications indicate that there is still a need for further efforts to enhance the clinical outcomes of this modality.

DISCOMFORT

Some degree of discomfort from any contact lens cannot always be completely eliminated. With scleral lenses it can be a consequence of apical corneal contact zones, limbal occlusion, an ill-fitting scleral zone or an early symptom of corneal hypoxia. Ortenberg et al. (2013) have shown that daily wearing time with scleral lenses can be significantly improved by taking brief breaks from lens wear every 4 to 5 hours.

BUBBLES

Elimination of air bubbles behind the lens is also not always possible, especially when the depth of the precorneal reservoir is not uniform. They may enter via non-aligned scleral zone sectors, but rarely disappear without removing and reinserting the lens. Lining the inside surface of the lens with a non-preserved viscous eye drop prior to inserting helps to reduce the problem. Bubbles entering the precorneal fluid reservoir via fenestrations sometimes cause clicking sounds, which can be very annoying. Instilling a viscous eye drop just at the site of the fenestration may offer a solution for a short period.

ACCUMULATION OF MUCUS

Scleral lenses sometimes generate oversecretion of mucus, which is trapped in the precorneal space. It can be globular or fine particulate matter. This is more of a problem with non-ventilated RGP lenses as there is some flushing action through a fenestration. Removal and reinsertion with fresh saline are necessary, and lining the back surface with a non-preserved viscosity agent appears to give an improvement in some cases. Instillation of mucolytic drops such as acetylcysteine before reinsertion may be considered.

CONJUNCTIVAL BLANCHING AND HYPERAEMIA

If localized, conjunctival blanching and adjacent hyperaemia may indicate compressive contact on the scleral zone. The limbus should be watched carefully for early signs of limbal vessel engorgement, which may be the precursor of corneal vascularization, but otherwise some hyperaemia is not a threat and may be impossible to alleviate.

CONJUNCTIVAL DISPLACEMENT AND THINNING

Displacement of the conjunctival flap over the limbus and peripheral cornea can occur, in particular with non-ventilated

RGP scleral lenses, if there is insufficient limbal clearance (Fig. 21.14). It does not cause a serious problem as reversal takes place on removal of the lens, but wearers notice it when looking in a mirror.

Alonso-Caneiro et al. (2016) observed that optimal-fitting miniscleral contact lenses worn for 3 hours resulted in significant tissue compression in young healthy eyes, with the greatest thinning observed superiorly, potentially due to the additional force of the eyelid, with a partial recovery of compression 3 hours after lens removal. Most of the morphological changes occur in the conjunctiva/episclera layers.

INFECTION

Infection does not appear to be a common problem with scleral lenses. Cleaning can be carried out effectively prior to both storage and insertion. A dry, clean case is a hygienic environment and unfavourable for bacterial replication. Zimmerman and Marks (2014) reported the case of neurotrophic keratitis in which scleral contact lenses improved vision from 6/30 to 6/6; however, due to poor lens care, an incident of microbial keratitis developed. Fortunately the lesion fully healed and the patient did not suffer additional vision loss.

GIANT PAPILLARY CONJUNCTIVITIS

Upper tarsal plate changes are seen sometimes with long-term scleral contact lens wear, but do not often appear to cause the typical discomfort described by soft lens wearers. This is presumably because there is no tarsal plate–lens edge interaction, and deposits are easily cleaned from rigid lens surfaces. The issue is clouded as atopy is a common coexisting pathology in keratoconus.

HYPOXIA

The corneal response to scleral lens wear has greatly improved with the introduction of gas-permeable materials (Bleshoy and Pullum, 1988; Pullum et al., 1990, 1991). Corneal thickness changes are demonstrably less (Mountford et al., 1994; Pullum and Stapleton, 1997). Hypoxia and consequent corneal vascularization have been significantly reduced. This means that, with the use of modern materials, overnight wear of scleral lenses can be considered (Rosenthal et al., 2000; Tappin et al., 2001; Smith et al., 2004; Vincent et al., 2016a). Compañ et al. (2014) have demonstrated that scleral lenses must be comprised of at least 125 Barrer of oxygen permeability and must be less than 200 µm thick to avoid hypoxic effects under open-eye conditions. Post-lens tear film layer should be below 150 µm to avoid clinically significant edema.

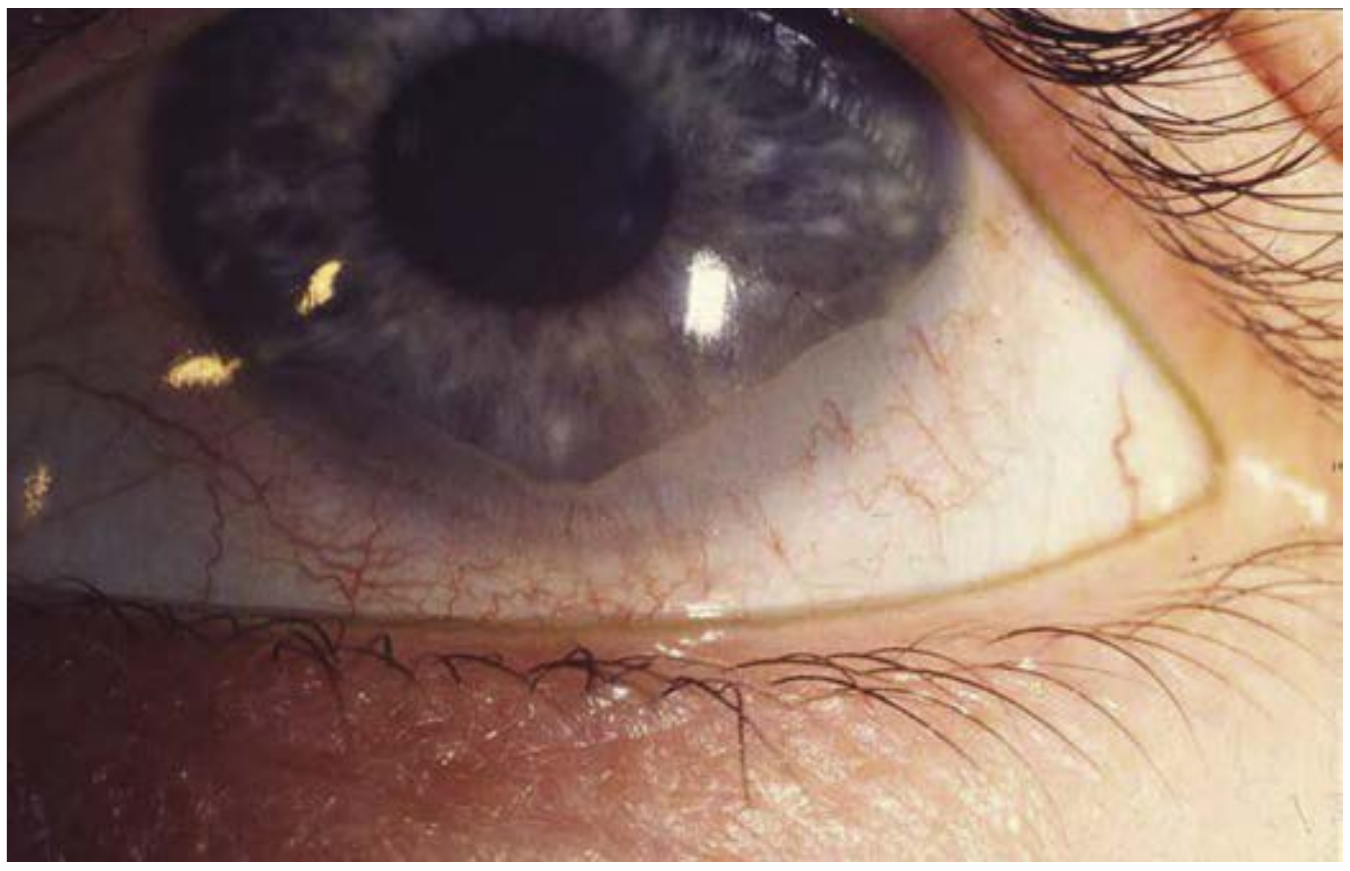

Fig. 21.14 Conjunctival displacement over the limbus is a common minor problem. It can be unsightly, but normality is restored immediately after removal of the lens.

ALTERATION TO CORNEAL NERVE STRUCTURE AND FUNCTION

Wang et al. (2015) examined changes in corneal nerve structure and function in two patient groups wearing long-term fluid-filled scleral lenses – those with distorted corneas or ocular surface disease. They observed that tear production decreased in patients with distorted corneas (21.2 ± 8.5 to 10.4 ± 4.6 mm; $p < 0.0001$) but did not change in patients with ocular surface disease (7.5 ± 5.2 to 8.7 ± 7.2 mm; $p = 0.71$). Corneal sensation increased in the distorted cornea group (45.6 ± 9.2 to 55.0 ± 5.6 mm; $p < 0.05$). There was no significant change in sensation in patients with ocular surface disease (45.0 ± 8.7 to 49.1 ± 14.8 mm; $p = 0.37$). Subbasal nerve density, subbasal nerve tortuosity, and stromal nerve thickness remained unchanged in both the distorted cornea and ocular surface disease groups after long-term wear ($p > 0.05$).

NEOVASCULARIZATION

Corneal vascularization is the long-term effect of chronic corneal oedema (Fig. 21.15). Corneal vessels do not necessarily cause a major visual loss, but have a tendency to leak lipid, and can cause a dense opacity. Sudden-onset visual loss can occur even if the vessels are apparently quite fine in calibre. Some absorption is possible after a time, but the rate is slower for older patients. There have been some cases when PMMA scleral lens-induced vascularization has been reversed on refitting with RGP scleral lenses, leaving only ghost vessels (Tan et al., 1995).

Some vessel ingrowth may be an acceptable complication if the visual indication for scleral lens wear is strong, and especially if the alternative management options are likely to be worse. The main concern is that any hypoxic changes may be

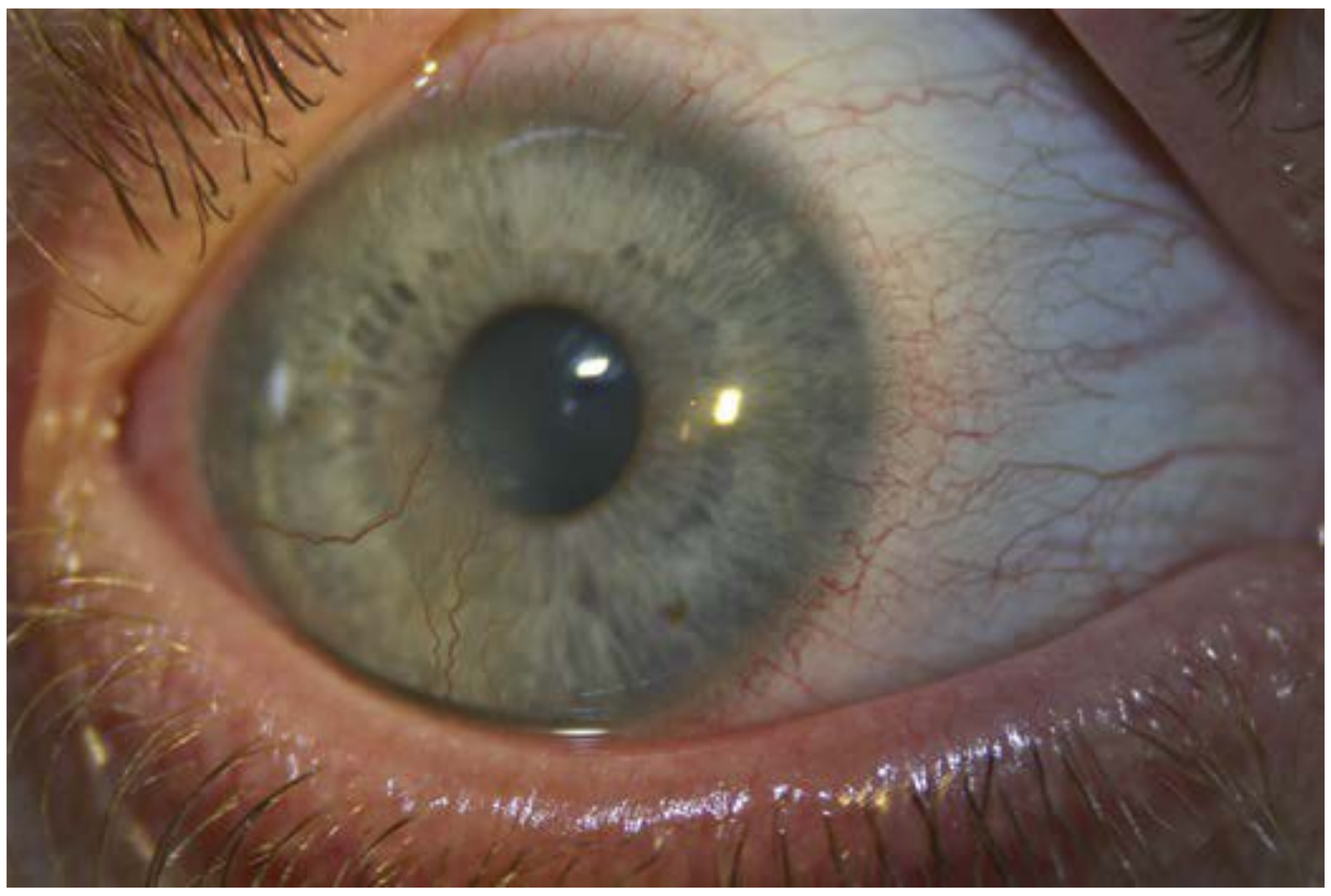

Fig. 21.15 Neovascularization after 5 years' rigid gas-permeable scleral lens wear. The indication for fitting was optical irregularities consequent to herpes simplex, so it is possible that the vessel growth was partly hypoxia and partly due to the disease process.

sight threatening: complacency must be avoided, but overstating the threat is not productive if there is a significant benefit from continued wear. It is possible that vascularization is self-limiting if compensating for an oxygen deficit. A small amount of vascularization is not sight threatening if, after the anticipated rate of progress, based on the existing extent of the vessels and assuming the same rate of progress, the vessels do not cross the visual axis within the patient's expected lifespan.

It must be recognized, however, that a bed of corneal vessels may increase the risk of later corneal transplant rejection. This is especially the case when the apex is eccentric, requiring a larger donor cornea that is in closer proximity to the limbal arcades. Careful monitoring and liaison with the ophthalmologist who may carry out future surgery are clearly essential.

CORNEAL DISTORTION

Vincent et al. (2016b) examined the influence of modern mini-scleral contact lenses – which land entirely on the sclera and overlying tissues – upon anterior corneal curvature and optics. They observed that, although corneal clearance was maintained throughout an 8-hour lens wear period, significant corneal flattening (up to 0.08 ± 0.04 mm) resulted, primarily in the superior mid-peripheral cornea. This caused a slight increase in against-the-rule corneal astigmatism (mean $+0.02/-0.15 \times 94$ for an 8 mm corneal diameter). Higher-order aberration terms of horizontal coma, vertical coma and spherical aberration all underwent significant changes ($p \leq 0.01$), which typically resulted in a decrease in RMS error values (mean change in total higher order RMS -0.035 ± 0.046 µm). There was no association between the magnitude of change in central or mid-peripheral corneal clearance during lens wear and the observed changes in corneal curvature ($p > 0.05$). However, East Asian participants displayed a significantly greater reduction in corneal clearance ($p = 0.04$) and greater superior–nasal corneal flattening compared with Caucasians ($p = 0.048$). Vincent et al. (2016b) warned that practitioners should be aware that corneal measurements obtained following miniscleral lens removal may mask underlying corneal steepening.

DEGRADATION OF THE LENS SURFACE

RGP materials are subject to spoilation and deposition. Polishing is possible, but this can be carried out only a limited number of times before the optic quality is lost. Resurfacing is also possible provided there is sufficient substance. There is much to be said for issuing a new lens before attempting to polish or resurface one that is currently worn.

Future Developments

Scleral lenses can reduce higher-order wavefront error associated with keratoconus; however, during wear the residual higher-order aberrations remain elevated, compared with normal eyes. Custom-designed scleral lenses can achieve this additional reduction in aberration. Scleral lenses are especially suited to this approach because of their stability on the eye. When a lens is not stable or is misaligned – as would be the case with a conventional rigid lens – aberration correction is reduced and can lead to an increase in higher-order aberration and a reduction in visual performance.

Marsack et al. (2014) examined the performance of state-of-the-art wavefront-guided scleral contact lenses on a sample of keratoconic eyes, with emphasis on performance quantified with visual quality metrics. They found that these lenses are capable of optically compensating for the deleterious effects of higher-order aberration concomitant with the disease and could provide visual image quality equivalent to that seen in normal eyes. This research points towards the more widespread adoption of such technology if it can be deployed for use at a reasonable cost.

Conclusion

Today's requirement for scleral lenses constitutes the smallest of all contact lens types, but their applications are often when other lens types are unsuccessful, or when the patient may face the alternative of potentially hazardous ocular surgery. It is vital to preserve clinical fitting skills as effectively as possible to avoid discredit due to too many unsatisfactory results. A relatively small number of practitioners need to be actively involved but those who may not wish to undertake the work personally can still be familiar with the application of scleral lenses so that suitable patients are recognized and referred for fitting.

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Access the complete references list online at http://www.expertconsult.com.

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22

Tinted Lenses

NATHAN EFRON | SUZANNE E EFRON

Introduction

Eye colour is universally recognized as an important and defining natural physical characteristic of the body human, and a contact lens is an effective vehicle for modifying or enhancing this appearance for those who wish to do so. More importantly, tints can be applied to contact lenses to help normalize the appearance of disfigured eyes and help improve vision in diseased eyes.

Tints have been applied to all forms of contact lenses since their invention over a century ago. In his original treatise in 1888, Fick clearly recognized the potential prosthetic benefits of contact lenses upon which opaque iris patterns and black pupils could be painted (Efron and Pearson, 1988). The inventor of the corneal lens, Kevin Tuohy, attempted to tint lenses, and Otto Wichterle, the inventor of the soft lens, was awarded two patents describing processes for tinting hydroxyethyl methacrylate (HEMA) lenses. This chapter describes the various applications of tinted lenses and current technology used for lens tinting.

Basic Options

An important initial consideration in deciding on the most appropriate tinted lens for a given patient is whether to use a rigid or soft lens. A particular lens type may be indicated for clinical reasons; for example, a rigid lens would be required in the case of a sighted eye with corneal distortion.

In general, rigid lenses are best suited for prosthetic use. An advantage of rigid lenses is that it is possible to paint unique designs and so effect a realistic iris appearance in terms of a more precise match of colour and iris features. A convincing cosmetic effect is difficult to achieve with a conventional rigid lens of, say 9.5 mm diameter, because it would not completely cover the cornea and iris, and move on blinking. These potential disadvantages can be obviated by fitting slightly tight, large-diameter lenses, semiscleral lenses or miniscleral lenses. In certain cases of extensive ocular disfiguration, painted scleral lenses may give the best result. Soft lenses have the advantage of offering full corneal coverage and stability on the eye, and are thus particularly suited for cosmetic use.

The applied tint can be translucent or opaque. The resulting lens may be wholly translucent if translucent tints alone are applied, semiopaque if opaque tints have been used on portions of the lens and completely opaque if opaque tints have been applied across the entire lens surface. A translucent tint allows certain wavelengths of light to pass through, thus effecting a colour change. Light passing through such a tint, and reflecting back off the iris, will be further modified such that the cosmetic effect is a combination of the colour of the translucent tint and the iris. Translucent tints can therefore be said to enhance or modify natural iris colours. This effect is successful only with relatively light-coloured irides.

Opaque tints can substantially or completely block the passage of light. A coloured pattern can be applied over a totally opaque base to effect a complete change of eye colour, while at the same time, for example, masking out underlying iris disfigurations. Thus, the primary cosmetic application of opaque tints is to change the colour of dark irides or have the prosthetic effect of restoring a normal appearance to a disfigured eye.

Tinted Lens Designs and Applications

Translucent and opaque tints are applied to rigid or soft lenses for a variety of reasons, which are outlined below.

HANDLING TINTS

Handling tints – which are also known as 'lens visibility tints' or 'locator tints' – are incorporated into soft lenses so that these lenses can be easily seen in the lens case or on a domestic surface if accidentally dropped (Fig. 22.1). Such tints are very light (between 5 and 15% absorption) and do not alter iris colour; however, they make the lens slightly more visible on the eye by virtue of the handling tint being noticeable where the lens edge impinges

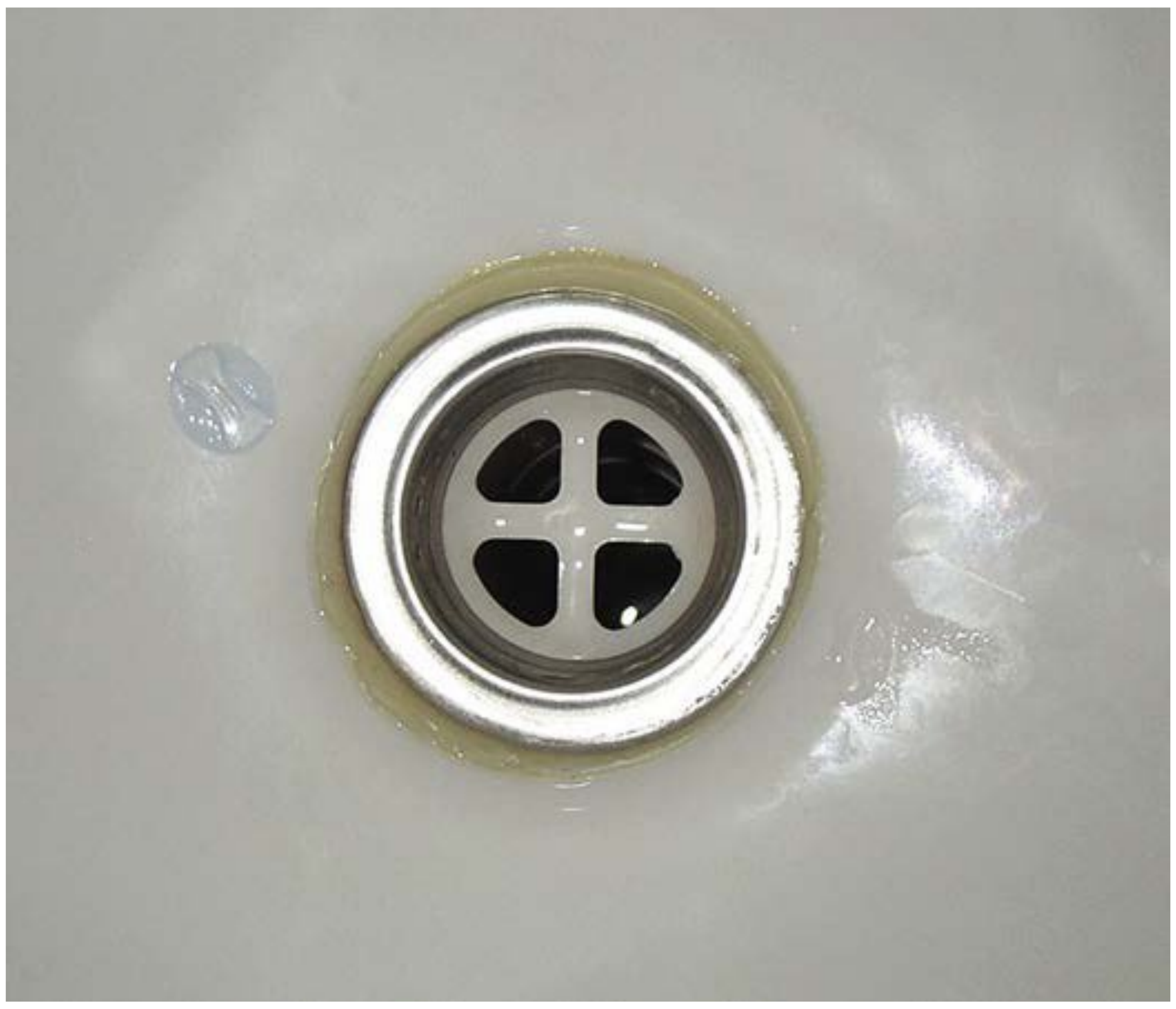

Fig. 22.1 Lenses dropped in a bathroom sink. The lens with the handling tint can be clearly seen at the half-past-9 position with respect to the drain hole, about 10 mm from the edge of the drain-plate. The lens without the handling tint is far less visible; its right-hand edge can just be detected at the 4 o'clock position, about 10 mm from the edge of the drain-plate.

over the sclera. Handling tints do not affect vision or colour perception. Some wearers find lens handling difficult as even with the pale handling tint the lenses can be hard to see. In those cases a cosmetic tinted lens may be fitted to enable easier handling.

COSMETIC TINTED LENSES

A cosmetic tinted lens can be defined as a lens that is designed to beautify an otherwise normal appearance. This can amount to enhancing eye colour with translucent tints, modifying eye colour with a combination of translucent and opaque tints, or completely changing eye colour with opaque tints. Cosmetic tinted lenses are considered to be a fashion accessory, and as such they are often worn by emmetropes. Indeed, most tinted lenses are produced for their cosmetic effect (Fig. 22.2). The most frequently used tints are aquamarine, blue, green and amber. As is the case with handling tints, cosmetic tints do not appreciably affect vision or colour perception (Tan et al., 1987), although patients may report an initial transient effect. The light transmission through cosmetic tinted lenses is usually in the range 75–85% (Harris et al., 1999).

A recently introduced concept in cosmetic lenses is the iris-enhancing ring. This is aimed at the Asian wearer, whose average horizontal visible iris diameter is 11.2 mm. The outer diameter of the limbal ring of the 1-Day Acuvue Define lens is 12.5 mm, thus enlarging the appearance of the eyes (Fig. 22.3).

PROSTHETIC TINTED LENSES

A prosthetic tinted lens is designed to normalize an otherwise abnormal appearance. Providing the patient does not have unreasonable expectations, the lenses are generally satisfactory in terms of wearing time, comfort and colour (Cole and Vogt, 2006). Typical cases for which such lenses are indicated include aftermath of trauma, ocular disease and congenital abnormalities (Fig. 22.4).

Visible deformities of the anterior ocular structures – in particular the cornea, iris and crystalline lens – can be effectively masked using dark (Luo et al., 2012) or opaque (Key and Mobley, 1987) tints. Specific tinting configurations can be tailored for different circumstances (Fig. 22.5); examples include:

- a painted iris and clear pupil for a sighted eye with a disfigured iris
- a painted iris and opaque pupil for a non-sighted eye
- a clear iris and opaque pupil for a non-sighted eye with a dense cataract.

THERAPEUTIC TINTED LENSES

A therapeutic tinted lens can be defined as a lens that is designed to treat an underlying defect or disease. Primary therapeutic applications of tinted contact lenses include reducing excessive photophobia and glare due to aniridia or other pupil anomalies (Olali et al., 2008)(see Fig. 22.4), albinism (Omar et al., 2012) or retinal disease (Severinsky et al., 2015), eliminating monocular polyopia due to trauma, eliminating binocular diplopia in squint (in cases where surgical and optical intervention is not viable or contraindicated) and managing variable nystagmus (Astin, 1998).

Several studies have shown that red tinted contact lenses may be useful in relieving the photophobia associated with a number of cone disorders, including achromatopsia (Zeltzer, 1979; Park and Sunness, 2004; Schornack et al., 2007). The dark-tinted glasses with side-shields and floppy hats usually used to manage these conditions are very conspicuous and can cause marked psychological morbidity in children. Rajak et al. (2006) fitted children with 70% brown contact lenses and observed marked improvements in their quality of life. Similar dark-brown tinted lenses were shown to help patients with Bothnia dystrophy (Jonsson et al., 2007), a variant of retinitis pigmentosa.

There are often secondary therapeutic benefits of tinted lenses designed for prosthetic use. These include the following examples: a lens with an opaque pupil masking a cataract but also eliminating disturbing light in a near-blind eye, a rigid lens with an opaque iris pattern fitted to a distorted cornea in a sighted eye also having the effect of improving vision by neutralizing corneal optics and the incorporation of appropriate lens power to correct vision, and a lens with an opaque iris pattern to mask aniridia in a sighted eye also reducing glare.

Opaque contact lenses have been used for occlusion therapy in amblyopia (Eustis and Chamberlain, 1996) and prosthetic

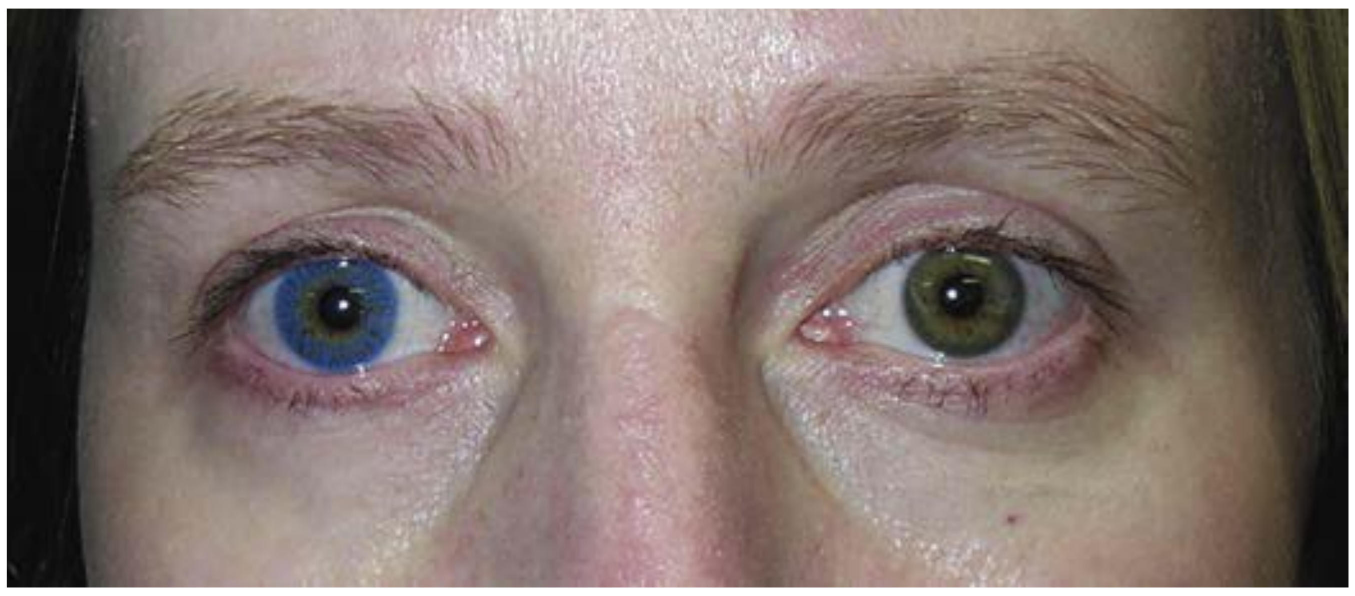
Fig. 22.2 Stunning cosmetic effect created by a lens with a blue dot-matrix tint in the right eye of a patient with identical irides in the right and left eyes (there is no lens in the left eye).

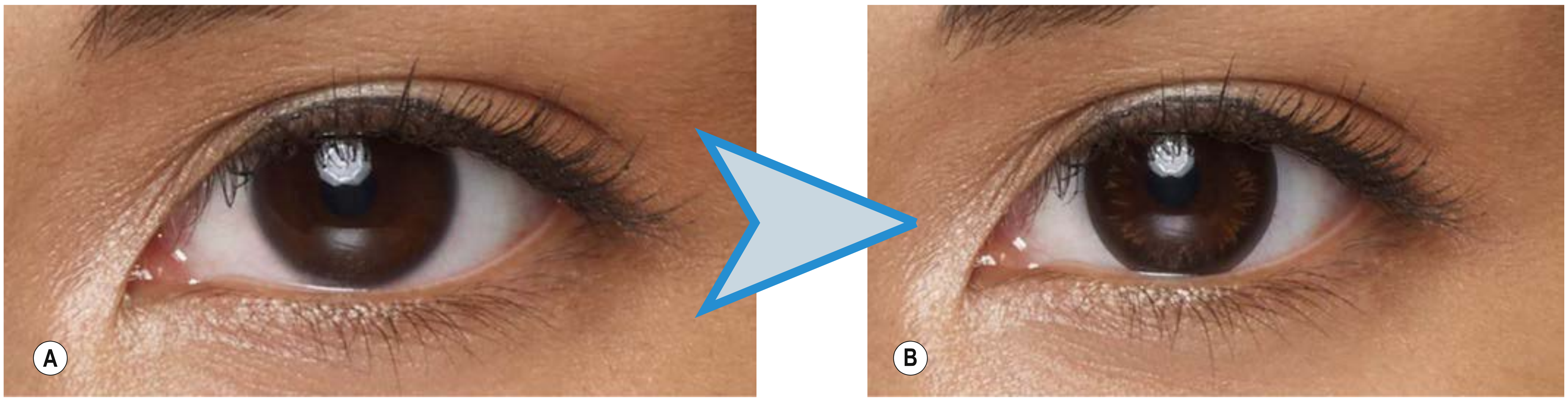

Fig. 22.3 Eye without (A) and with (B) a lens with iris-enhancing ring. (Courtesy of Johnson & Johnson Vision Care.)

lenses have also been trialled for this purpose. The degree of penalization can be varied with different iris print patterns and opaque pupil sizes. Peripheral fusion can be preserved with some lenses (Collins et al., 2008).

PERFORMANCE-ENHANCING TINTED LENSES

Colour Vision

Monocular prescription of red tinted lenses to enhance colour vision in colour-defective patients has long been advocated; however, their use is controversial. X-Chrom lenses have a dark red pupil, the diameter of which may be varied to suit individual needs. One eye receives a different luminance and chromatic signal from the other eye and through a process of retinal rivalry a wider range of colours can apparently be interpreted.

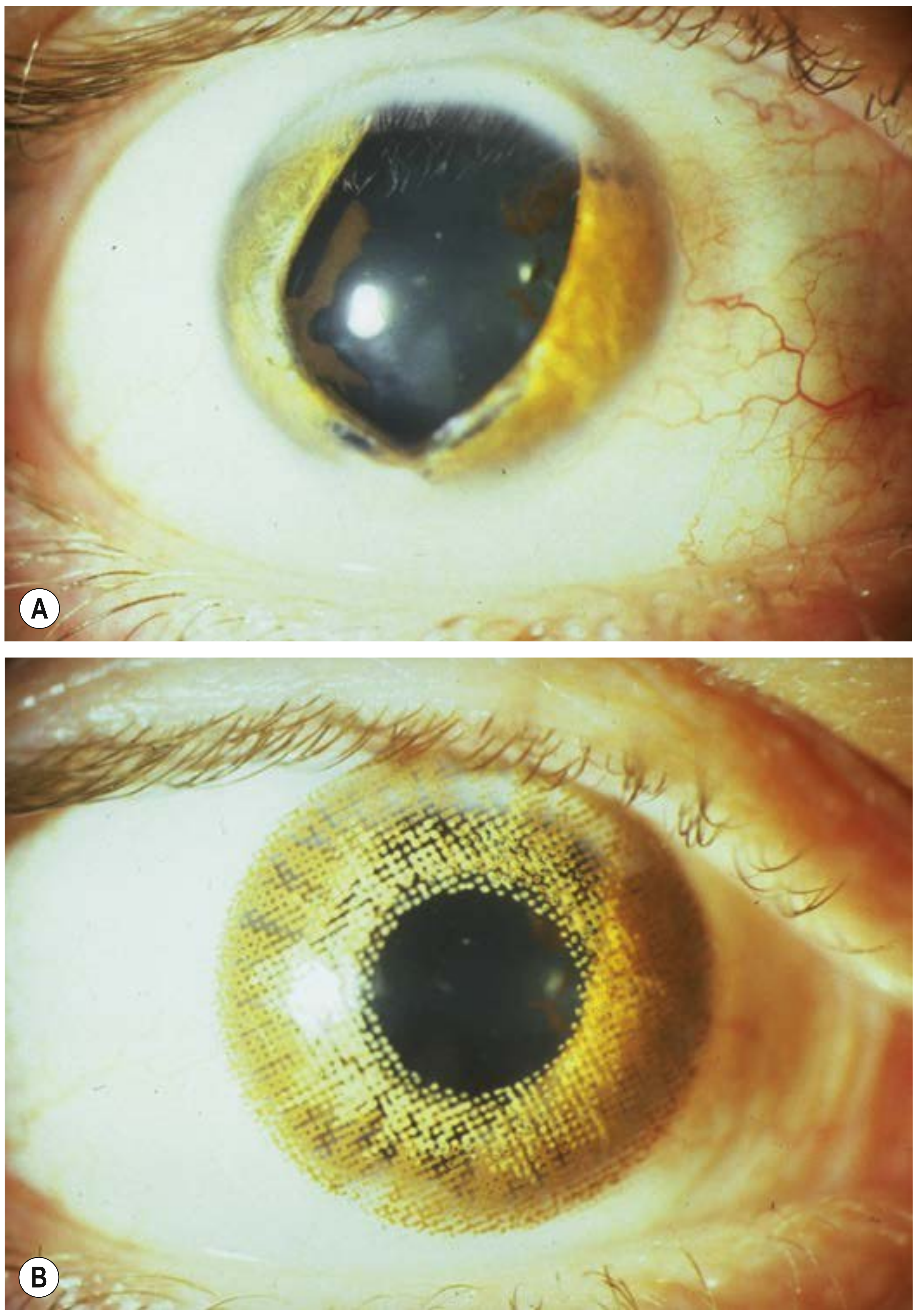

Fig. 22.4 (A) Trauma has resulted in partial aniridia, giving rise to an unsightly appearance and excess glare. (B) An opaque dot-matrix print soft lens offers the prosthetic advantage of an improved appearance and the therapeutic benefit of reducing excess glare. (Courtesy of H. J. Völker-Dieben, Bausch & Lomb Image Collection.)

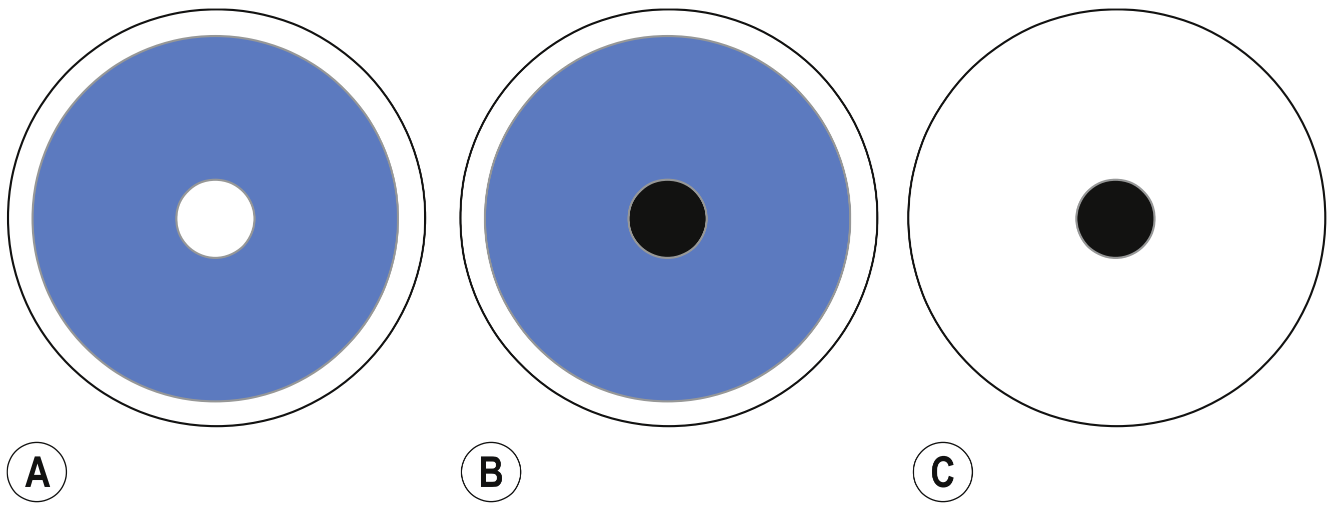

Fig. 22.5 Three basic lens tint configurations for combined prosthetic/therapeutic effects. (A) Clear pupil and opaque iris; (B) opaque pupil and opaque iris; (C) opaque pupil only.

Swarbrick et al. (2001) showed the ChromaGen lens significantly reduced Ishihara error rates, particularly for deutan subjects, but had no significant effect on Farnsworth lantern test performance. Similarly, Mutilab et al. (2012) reported similar findings for both light-red and dark-red lenses; colour-defective patients wearing such lenses gave near-normal results on Ishihara plates but the FM100Hue test did not show any improvement with either tinted lens. There are medico-legal implications in prescribing these lenses to enable patients to pass the colour vision tests required in occupations with colour-vision-related restrictions.

Dyslexia

Various tinted lenses have been devised to cure dyslexia and to alleviate migraine. These can also technically be described as therapeutic applications, although in most cases it appears that improvements are attributed to a placebo effect rather than a true therapeutic effect.

Sport

Sport-tinted contact lenses have become available to athletes in an attempt to improve performance by enhancing contrast. Two shades are advocated for different sports. An amber tint is suggested for fast-moving ball sports such as football, rugby, tennis and baseball. A grey-green tint is suggested for golf, running and training. The now-discontinued Amber and Gray-Green Nike Maxsight lenses had 50% and 36% visible light transmission, respectively.

Although there may be statistically significant differences in contrast when sport-tinted contact lenses are worn, there does not appear to be evidence that the lenses provide any clinically significant difference when considering contrast enhancement (Porisch, 2007; Cerviño et al., 2008; Zimmerman et al., 2011). However, it has been suggested (Erickson et al., 2009; Horn et al., 2011) that the Maxsight Amber and Gray-Green lenses provide better contrast discrimination in bright sunlight, better contrast discrimination when alternating between bright and shaded target conditions, better speed of visual recovery in bright sunlight and better overall visual performance in bright and shaded target conditions compared with clear lenses. These lenses are no longer produced.

Schürer et al. (2015) investigated the impact of yellow and orange Wöhlk ‘Sport Contrast’ tinted contact lenses on colour discrimination using the Erlangen colour measurement system in a study with 14 and 16 subjects, respectively. Both lenses caused a shift of the reference colour towards higher-saturated colours. Colour discrimination ability with the yellow- and orange-coloured lenses was significantly enhanced along the blue-yellow axis, in comparison with the reference measurements without a tinted filter. Along the red-green axis only the orange lens caused a significant reduction of colour discrimination threshold distance to the reference colour. They concluded that yellow- and orange-tinted contact lenses enhance the ability of colour discrimination.

PROPHYLACTIC TINTS

The purpose of a prophylactic tint is to prevent injury or disease of the eye. The primary prophylactic application of tinted lenses is protection from excess ultraviolet (UV) light. Lenses with UV protection tints may be beneficial to lens wearers who are frequently exposed to UV radiation, such as those who:

- pursue an active outdoors lifestyle, especially near snow, sand and sea
- work outdoors (such as professional tennis players)
- use photosensitizing drugs
- are often exposed to artificial UV sources during work or recreation
- are aphakic.

Some argue that everyone can benefit from UV tints to prevent chronic ocular damage. Non-tinted lenses and lenses with standard cosmetic tints transmit light down to 230 nm and thus do not provide acceptable UV protection (Tønnesen et al., 1997; Harris et al., 1999). Lenses with special UV tints were found by Harris et al. (1999) to block light lower than about 350 nm from entering the eye, thus affording the desired protective effect. Osuagwu and Ogbuehi (2014) reported that the UV-blocking characteristics of five lenses evaluated performed equally well across the UV spectrum. Otman et al. (2010) measured the UV transmission spectra of 30 'UV protective' contact lenses at 5 nm intervals between 290 and 400 nm and concluded that most lenses did not provide significant UV protection in the UVA range. Rahmani et al. (2014) noted a statistically significant difference among four contact lenses tested for the visible, UV-B and UV-A portions of the spectrum.

The UV transmittance characteristics of a range of daily disposable and silicone hydrogel contact lenses were investigated by Moore and Ferreira (2006). They noted that even those contact lenses not incorporating a UV-blocking monomer still demonstrated some attenuation of the UV spectrum and can therefore also serve to reduce the amount of UV incident at the anterior ocular surface.

Patients must, however, be warned of the limitations of UV-tinted contact lenses. For example, solar keratitis can occur in exposed regions of the cornea in UV-tinted rigid lens wearers, and the conjunctiva is susceptible to solar damage in both soft and rigid lens wearers. Accordingly, patients should be advised to wear UV-protecting sunglasses or goggles during prolonged periods of UV exposure, and to protect exposed regions of skin in extreme conditions. Contact lenses may be the only form of UV protection possible in situations where spectacles cannot be worn, for example for sports such as surfing.

THEATRIC TINTED LENSES

Lenses can be designed and tinted – typically with opaque agents – to create dramatic or theatrical effects. Such lenses are also known as 'costume' or 'party' lenses. Effects such as wolf eyes (Fig. 22.6), national flags, hearts, stars and smiley faces can be created, and some companies market afocal lenses specifically for this purpose.

Although these lenses are viewed as a fashion accessory, potential users must be advised to have a thorough initial eye examination to check that their eyes are suitable for wearing contact lenses, and that the fit is satisfactory. Regular aftercare examinations are also recommended. Users should also be warned that such lenses should never be shared with anyone else because: (1) the contact lenses may not fit, or be contraindicated, in another person; and (2) there is a danger of cross-contamination and infection (Johns and O'Day, 1988; Steinemann et al., 2003; Connell et al., 2004; Lee et al., 2007; Kerr and Ormonde, 2008; McKelvie et al., 2009; Chang et al., 2010; Guyomarch et al., 2010; Niyyati et al., 2010; van Zyl and Cook, 2010; Sauer et al., 2011; Singh et al., 2012; Ray and Kim, 2013; Abdelkader, 2014; Mahittikorn et al., 2016). Certainly, concern has been expressed regarding the unsupervised purchase of tinted lenses through unauthorized or non-licensed sellers (Gaiser et al., 2016).

Opaque lenses with clear pupils may also cause changes in corneal topography during wear, which can take up to 150 minutes to recover. Wearers of such lenses need to be made aware of the potential for reduced visual performance, both during lens wear and for several hours afterwards (Voetz et al., 2004).

IDENTIFICATION TINTS

Lens buttons are colour coded with light tints by some manufacturers who supply a wide range of products so as to facilitate correct product identification at the lens-fabrication stage. Tints are sometimes used as lens identification imprints and toric lens axis location marks.

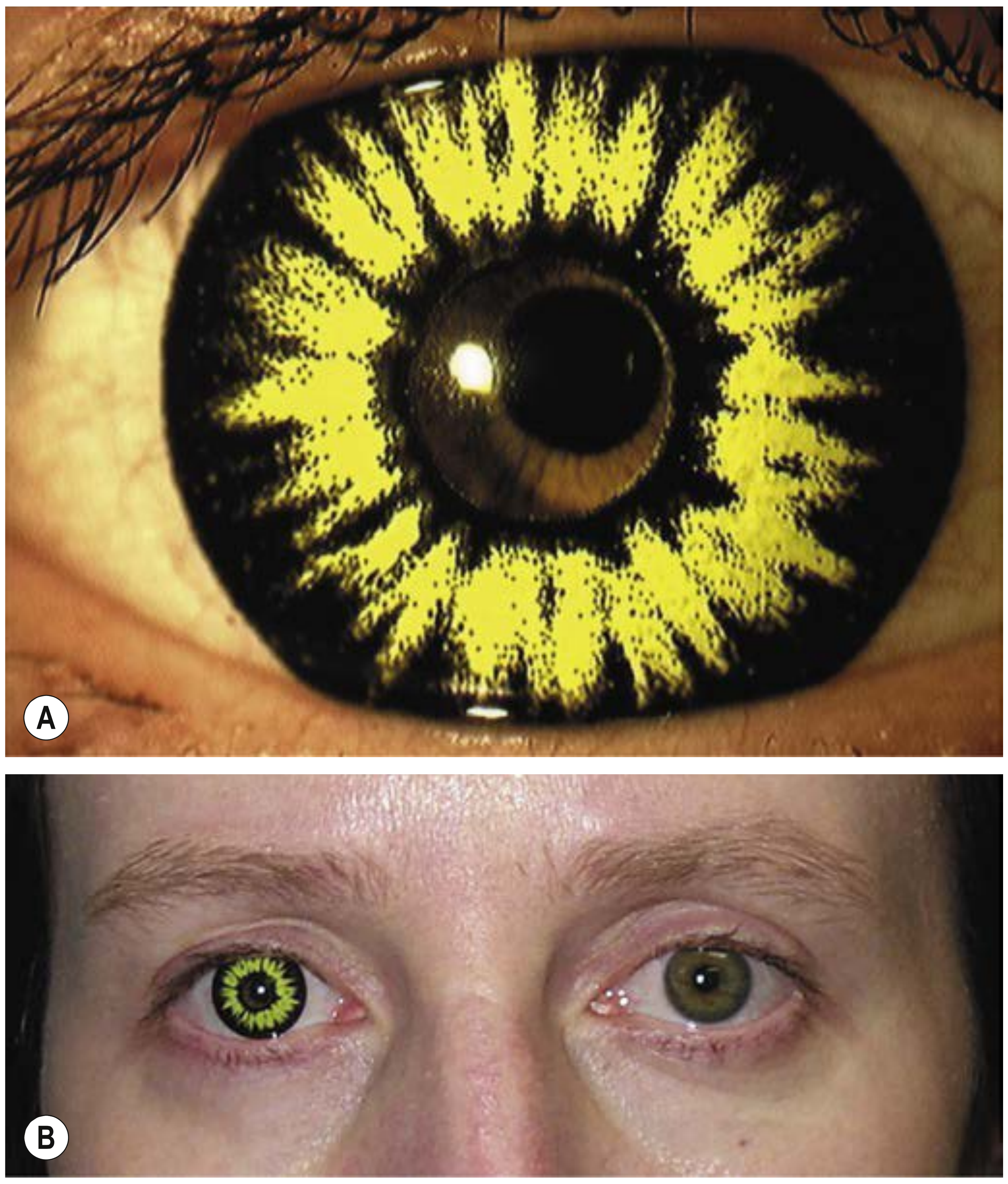

Fig. 22.6 Theatric 'wolf-eye' lens. (A) The clear pupil of the lens featured here is slightly decentred with respect to the natural pupil. (B) Viewed at arm's length, the 'wolf-eye' lens is seen in the right eye of a patient with identical irides in the right and left eyes (there is no lens in the left eye). The yellow tint contains fluorescent dyes so that the lens glows in the dark under ultraviolet radiation.

Manufacture

Numerous ingenious chemical processes and manufacturing techniques have been devised for tinting contact lenses (Meshel and Smith-Kimura, 1996). Concepts have been variously 'borrowed' from industries as diverse as fabric dying, map making, leather decorating, paper printing, photography and lithography. A vast patent literature protects the proprietary interests of many of those who have devised the various processes. The general principles underlying some of the key techniques for producing translucent, opaque and combination tints are outlined below.

TRANSLUCENT TINTS

Translucent tints can be created using four basic techniques – dye dispersion tinting, vat dye tinting, chemical bond tinting and printing.

Dye Dispersion Tinting

This method is used primarily to tint rigid lenses. A dye or pigment is mixed into the polymer matrix by adding the dye to the monomer mixture prior to polymerization, or by adding the dye to the polymer and then mixing to disperse the colour. This results in an evenly distributed, stable dye. The disadvantages of this process are:

- It is not possible to vary the distribution of tint across the lens (e.g. to create a clear pupil).
- The density of tint is proportional to lens thickness (Fig. 22.7).
- This process is unsuitable for soft lenses because the dye, which is non-water-soluble, can leach out from the polymer during hydration.

Vat Dye Tinting

This process is suitable for soft lens tinting. The finished contact lens is soaked in a water-soluble dye for a fixed amount of time at a specified temperature. The lens is then exposed to air, rendering the dye insoluble and trapped within the lens matrix. Because the dye enters the lens surface only to a depth of about 10 μm, the lens will appear to have a uniform tint across its entirety, the intensity of which will be independent of optical power (see Fig. 22.7). The dye is held in position by strong absorptive forces, resulting in a stable, permanent tint (Lutzi et al., 1985). The dye can be extracted only by the use of powerful solvents. This technique can be used for tinting prosthetic silicone hydrogel lenses.

Chemical Bond Tinting

In this process, a strong covalent chemical bond is formed between the dye chromophore and the polymer. The technique involves soaking the lens in a dye solution, in the presence of a catalyst, for a fixed time at a specified temperature. The lens then needs to be put through a series of extraction processes to remove any residual unreacted agents. The result, as with vat dye tinting, is a stable, uniform tint (Fig. 22.8).

Printing

Dye can be placed on the lens surface in a controlled manner using a printing process similar to that used for ink printing on paper. In this way, realistic iris patterns containing many colour elements can be applied, and the pupil region can be kept clear.

Alcon has developed a unique printing process to produce cosmetic silicone hydrogel contact lenses – known as Air Optix Colors – which are capable of altering or enhancing iris colour. A clear layer of polymer is applied to the base curve of a male mould in the region where iris coloration is to be located (i.e. most of the lens surface except for the central 5 mm optic zone). The clear layer, which constitutes the back surface of the lens, ensures that pigments are not exposed directly to the cornea during wear.

Three layers of coloured inks – in the form of concentric rings of varying diameter that form different potions of the iris – are then applied separately over the clear polymer using a 'pad-printing' process. The three partially overlapping concentric layers are: (a) an outer ring, which defines and emphasizes the iris, (b) the main body of the iris, which contains the primary dyes that transform eye colour, and (c) an inner ring, which brightens the eye and adds a sense of depth (Fig. 22.9).

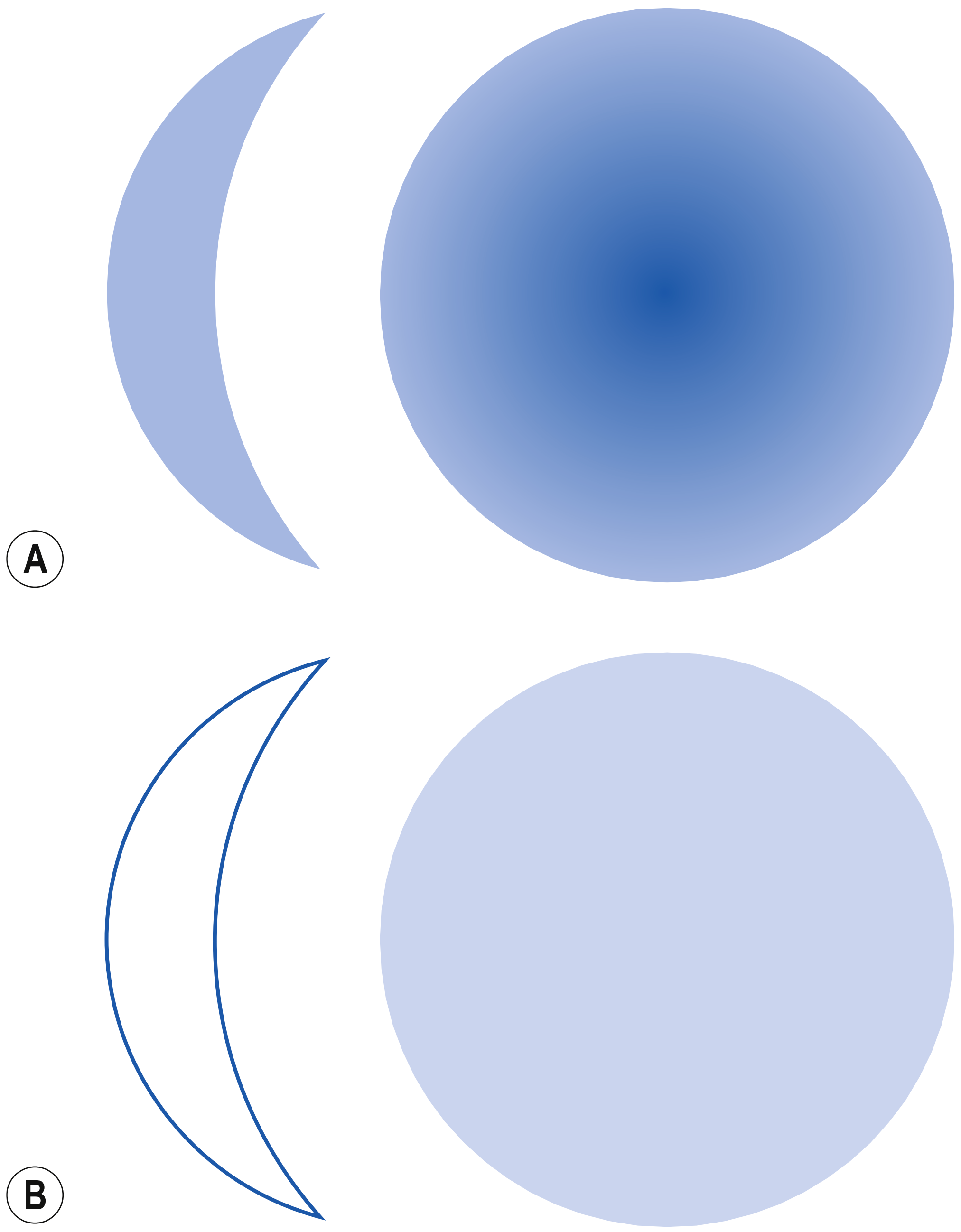

Fig. 22.7 Effects of tint process on lens appearance. (A) Dye dispersion tinting of a plus-powered lens can result in greater tint density towards the lens centre. (B) Vat dye and chemical bond tint processes result in an even tint distribution across the lens.

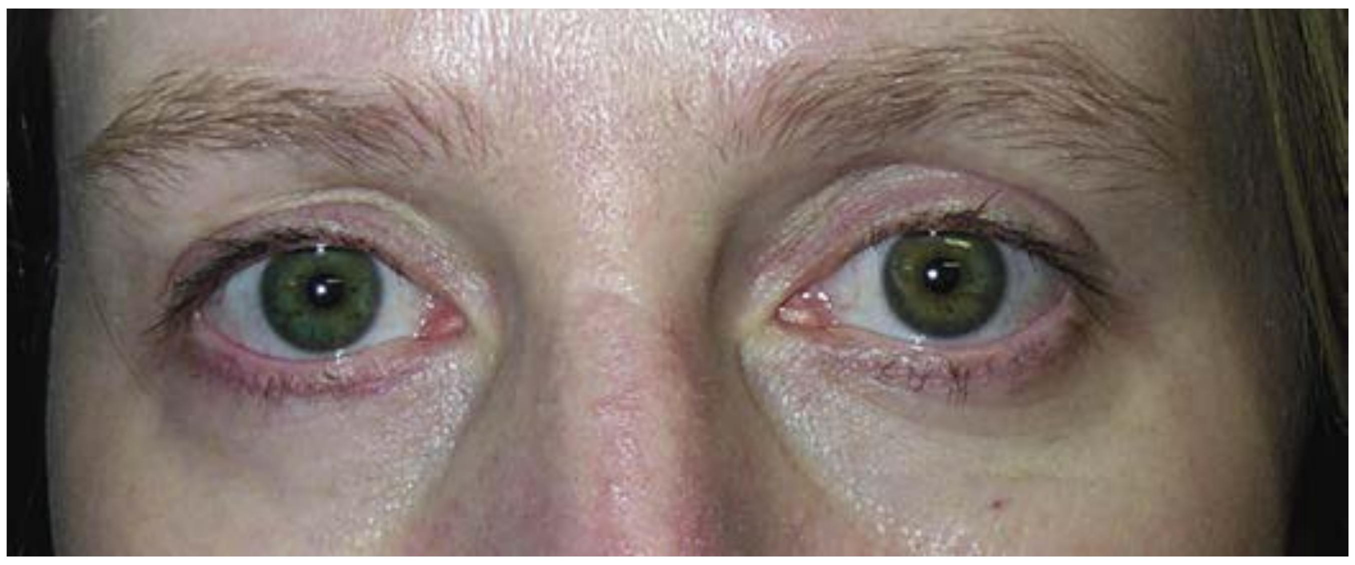

Fig. 22.8 Subtle cosmetic effect created by a light aqua chemical bond tint in the right eye of a patient with identical irides in the right and left eyes (there is no lens in the left eye).

The mould with the resulting 'triple-stack' of printed layers is then exposed to UV light, partially cross-linking the colour, yet leaving a portion available for further cross-linking to lotrafilcon B polymer, which is added to form the front surface of the lens. The ink is therefore sealed within the lens and cannot removed during cleaning cycles. The lenses are then plasma treated to enhance surface wettability.

Coloration is achieved using various combinations of the following colour additives: yellow, red and black iron oxides; phthalocyaninato copper (blue) and green; and titanium dioxide. A range of nine different colour effects are available; these include five 'subtle' colours: pure hazel, blue, green, grey and brown; and four 'vibrant' colours: honey, brilliant blue, gemstone green, and sterling grey (Fig. 22.10).

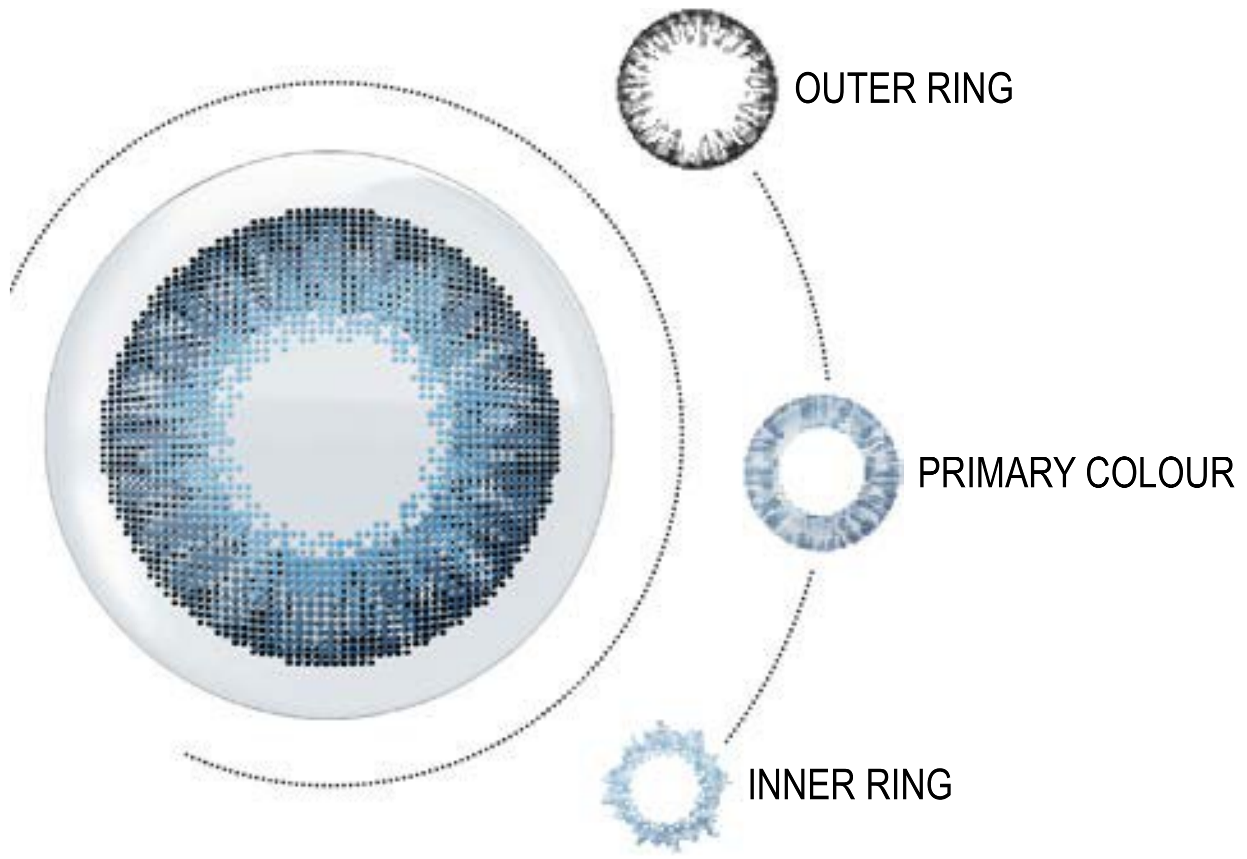

Fig. 22.9 Three partially overlapping concentric layers that combine to form the iris pattern of the Alcon Air Optix Colors lens. (Courtesy of Alcon.)

OPAQUE TINTS

Opaque tints can be applied using dot-matrix printing, laminate constructions and opaque backing.

Dot-matrix Printing

This technique involves applying a matrix pattern of small opaque dots to the front surface of the lens (Fig. 22.11). The dots are created by bonding an opaquing agent, such as titanium dioxide, and a colouring agent, which may be a pigment or dye, to the lens surface. A binding polymer, such as di-isocyanate, is used to form a strong chemical bond between the opaque tinted agent and the lens surface. The final cosmetic effect will be a combination of dot matrix pattern and reflections from the natural iris between the opaque matrix dots (Fig. 22.12).

Laminate Constructions

An opaque tinted iris pattern can be incorporated within the lens using a laminate construction. An iris pattern is painted, using opaque dyes and tints, onto the surface of an unhydrated HEMA button that has been lathed to the curvature of the intended finished lens. A second pouring of HEMA over the top of this pattern is effected. Once set, the laminate button is lathed to create the finished lens form, which is then hydrated in the usual way. The advantage of this process is that the painted features are encapsulated, and therefore protected, within the lens. The disadvantages are that the lens is thicker, thus reducing oxygen transmissibility, and the tensile properties of the lens are altered, which can affect fitting characteristics (Fig. 22.13).

A variation of laminate construction is known as 'sandwich technology'. The top and bottom layers of clear HEMA are copolymerized with a thin middle layer of coloured non-toxic

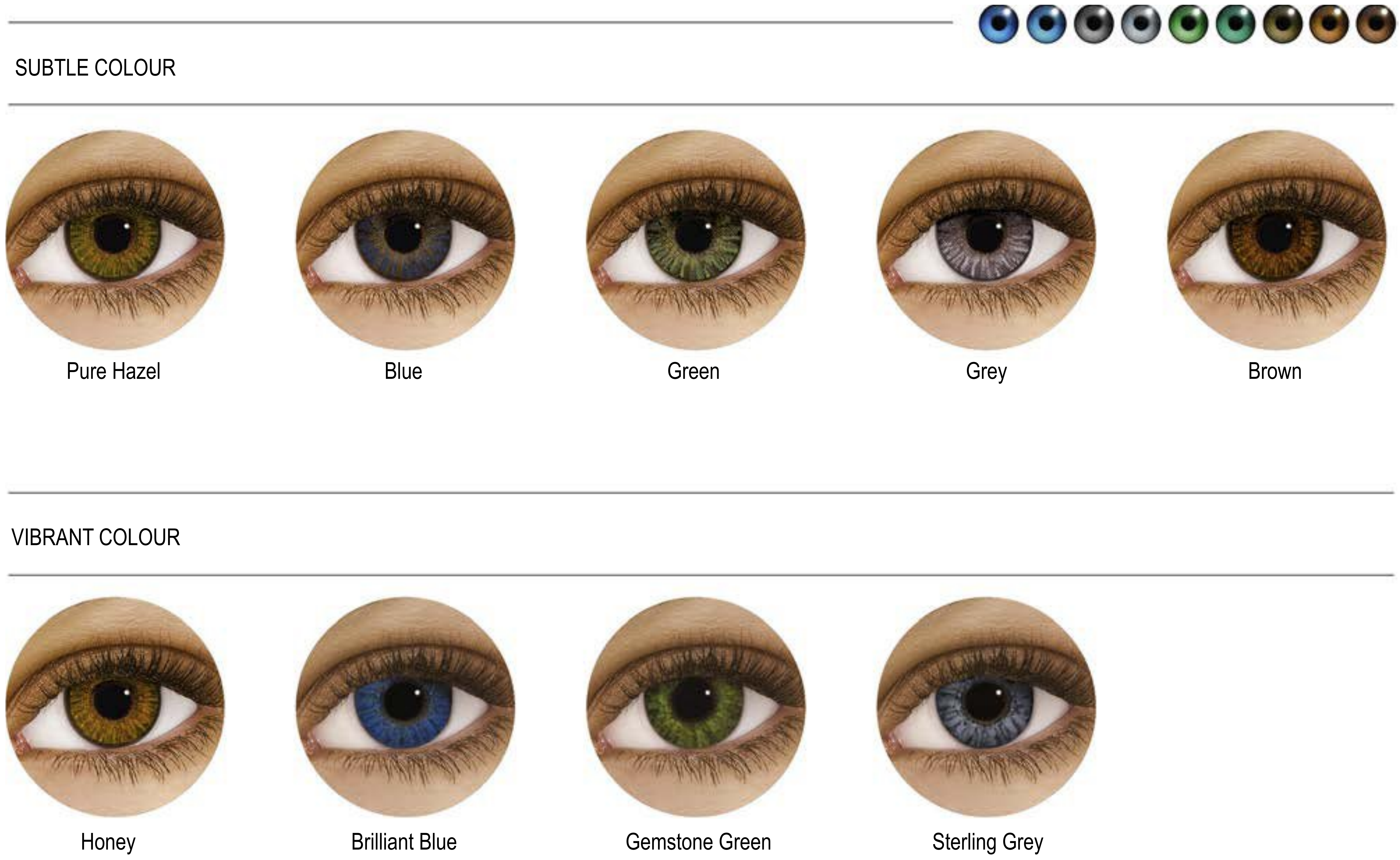

Fig. 22.10 The five 'subtle' and four 'vibrant' colours in the Alcon Air Optix Colors range. (Courtesy of Alcon.)

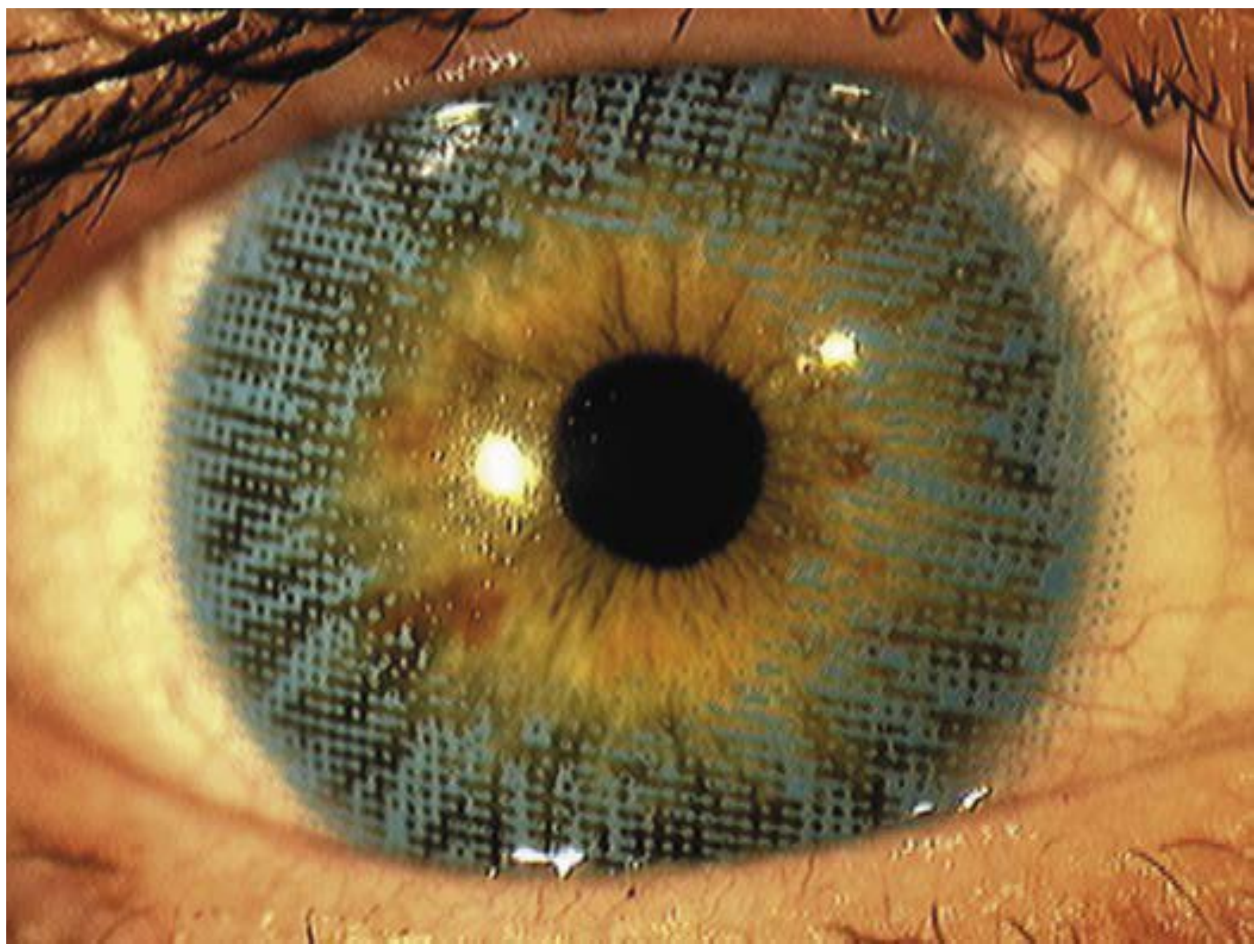

Fig. 22.11 Lens with a matrix of opaque blue dots (the appearance of this lens at arm's length can be seen in Fig. 22.2).

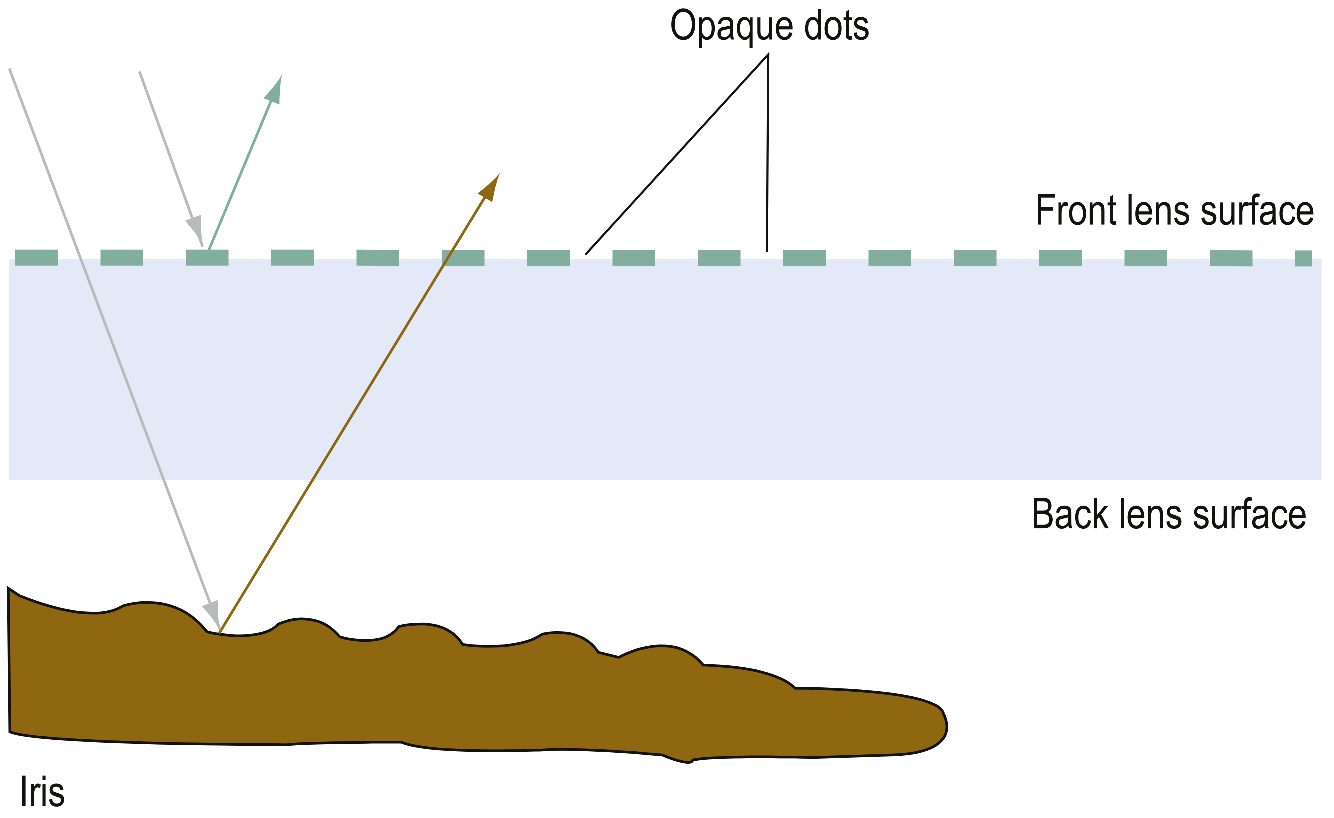

Fig. 22.12 The cosmetic appearance of a dot-matrix lens will result from a combination of the colour of the dots on the lens surface and the natural colour of the underlying iris.

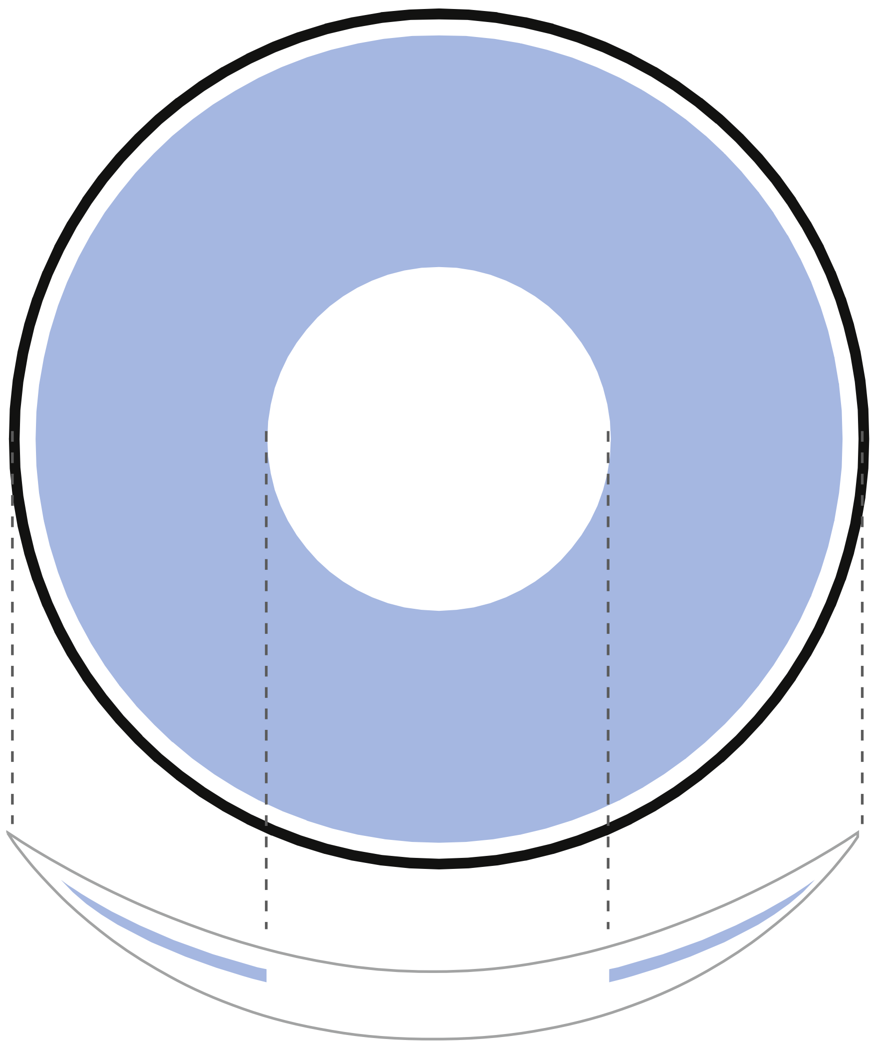

Fig. 22.13 Laminate tinted lens construction, whereby the opaque iris tint is essentially encapsulated within the centre of the lens. The laminate is absent from the pupillary region and lens periphery.

pigments, allowing the composite button to be lathed and then hydrated into an ultrathin lens design. An alternative approach is to use non-coloured opaquing agents to create an iris pattern in the centre of the two HEMA buttons, and then tinting the top HEMA section to create the desired cosmetic coloration.

Opaque Backing

The matrix of a lens can be tinted with a translucent dye, and an iris pattern and black pupil are applied to the back surface of the lens using opaque paints. In this way, the entire back surface of the lens is rendered opaque; light reflects off the opaque layer and the coloured appearance is created from the translucent tint in the lens body (Fig. 22.14).

Surface Characteristics of Tinted Tenses

A number of studies have examined the surface characteristics of opaque tints that appear on the surface of tinted lenses. Hotta et al. (2015) analysed the surfaces and principal elements of the colourants of five commercially available tinted lenses using scanning electron microscopy with energy-dispersive X-ray analysis. They observed that, in some lenses, colourants were found on the front and back surfaces of lenses, with uneven patterns apparent in dot-matrix design lenses. Colourants used in all lenses contained chlorine, iron, and titanium. In the magnified scanning electron microscopy images of one lens, chlorine is exuded and spread. The authors suggested that colourants might be deposited on the lens surface and consist of elements that have tissue toxicity.

Jung et al. (2016) investigated ten different types of tinted soft contact lenses using light microscopy, focused ion beam milling and scanning electron microscopy, Fourier-domain optical coherence tomography and atomic force microscopy. They noted that when pigment particles were buried below the front surface there was no significant impact on surface roughness. However, all tinted lenses with surface pigment had a significant difference in roughness between front and back surfaces at the pigmented area.

Chan et al. (2014) reported higher levels of adherence of pseudomonas aeruginosa to 13 of 15 different brands of tinted contact lenses tested, compared with adherences to clear lenses, and Ji et al. (2015) observed an association between surface roughness and bacterial adhesion on tinted lenses. These findings have implications in terms of the importance of maintenance and disinfection of tinted lenses, and an increased risk of infection during wear of such lenses.

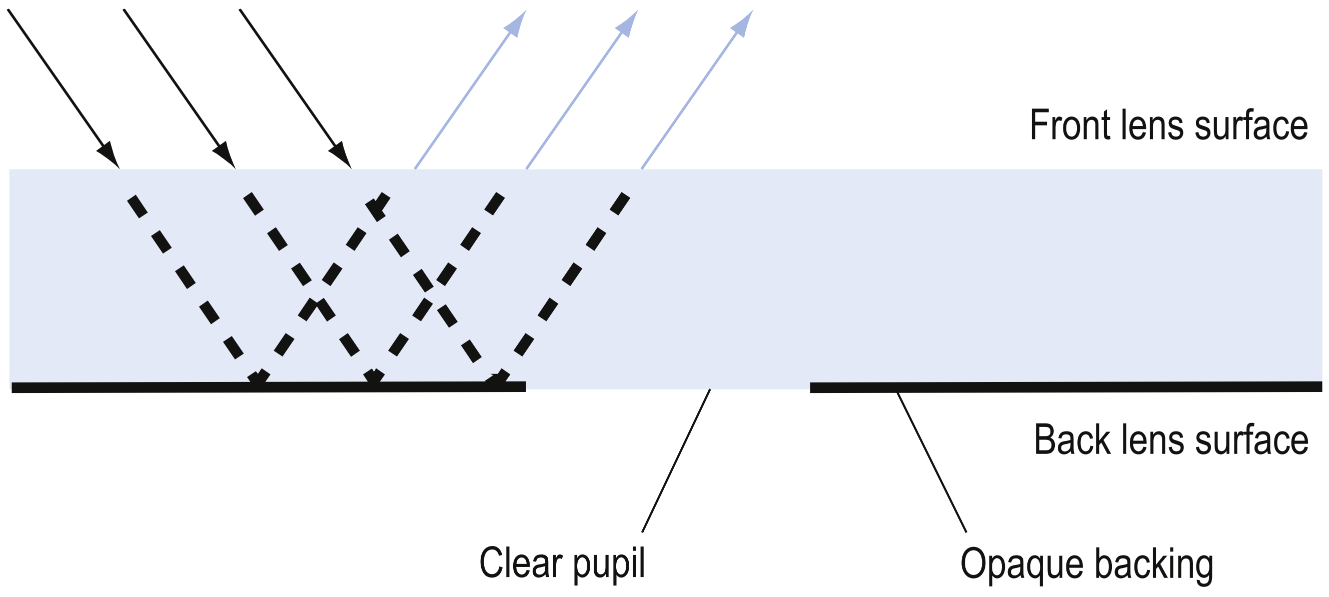

Fig. 22.14 Light reflects off an opaque backing and returns through the tinted body of the lens, giving the iris a coloured appearance.

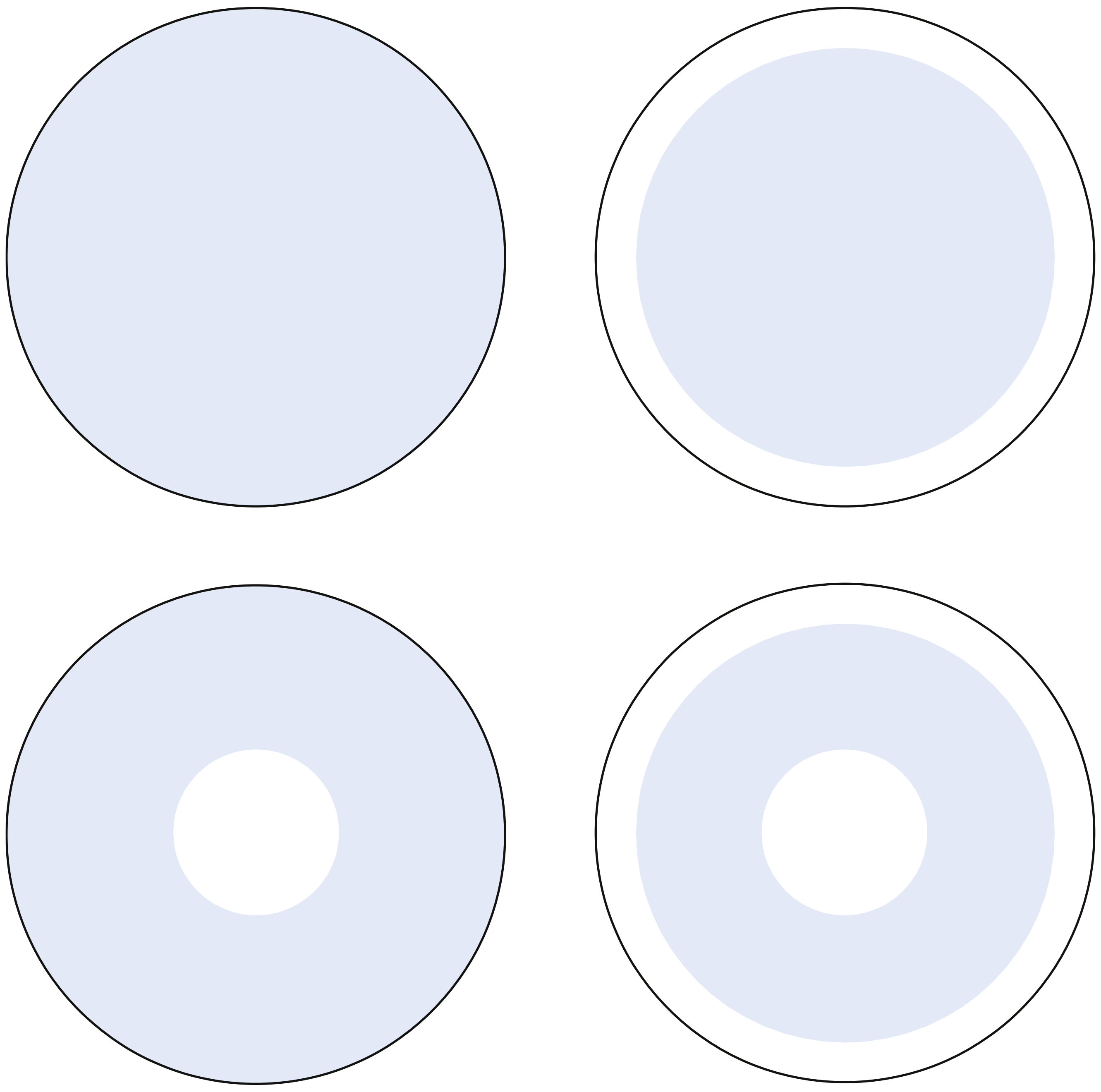

Fig. 22.15 Four basic combinations of cosmetic tint.

Clinical Considerations

The distribution of tint and method of manufacture of tinted lenses have certain clinical ramifications of which the practitioner needs to be aware. These considerations are outlined below.

TINT DISTRIBUTION

Selective distribution of a tint across the surface of lenses designed for cosmetic use allows four basic combinations (Fig. 22.15). The variables are: (1) whether or not to leave a 1.5 mm band clear of tint around the lens edge; and (2) whether or not to have a clear pupil. A full tint covering the pupil appears more natural, but this creates a small but constant tinting effect on vision. A clear pupil eliminates the visual effect, but introduces problems of obtaining good alignment and size-matching between the clear pupillary zone of the lens and the natural pupil of the eye, the latter varying with ambient lighting (Fig. 22.16). Tints that extend to the edge of the lens are cosmetically unsatisfactory because they are visible against the white sclera at the limbus.

LENS FITTING

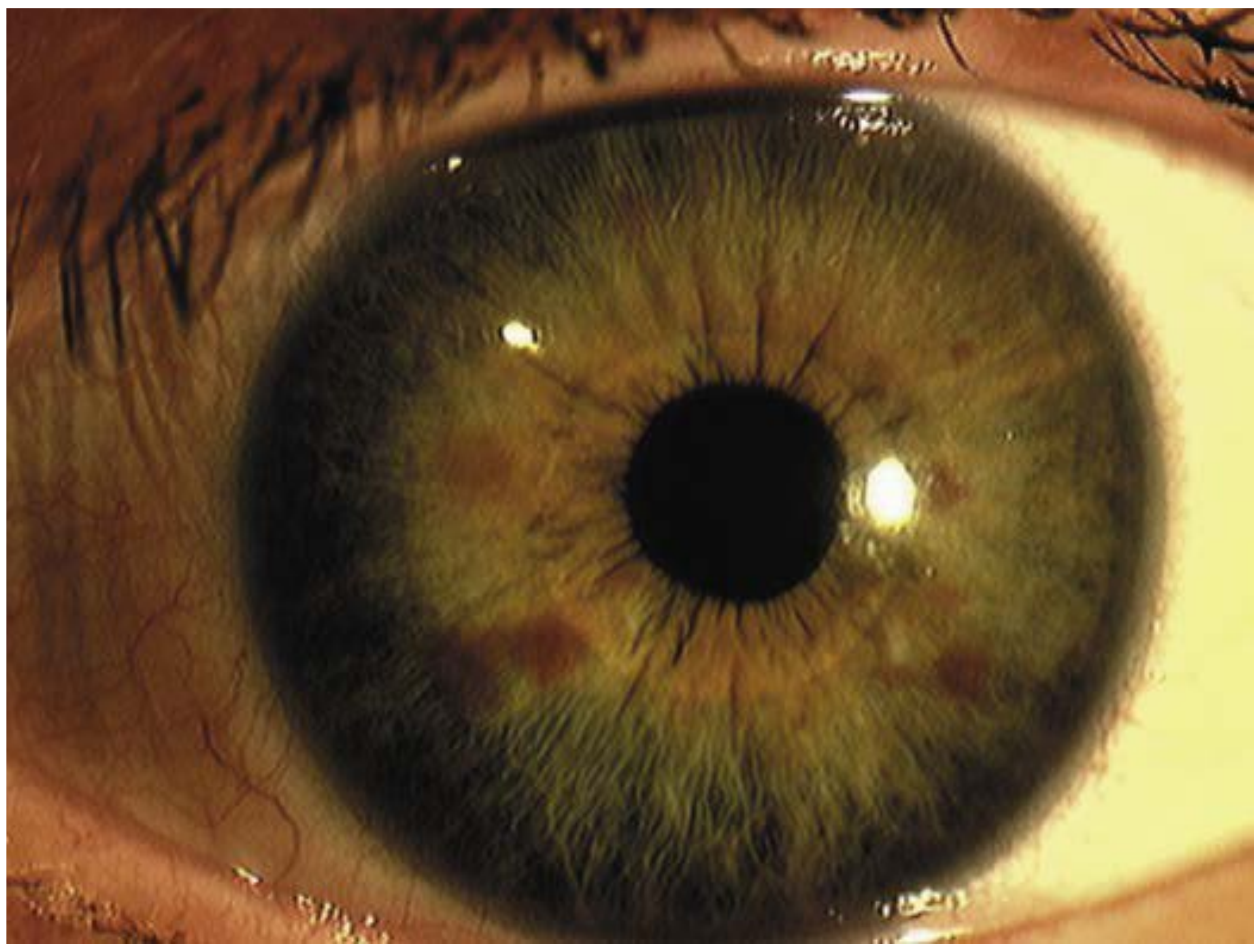

Fig. 22.16 Blue tint with a clear pupil. Here in bright light, the natural pupil is much smaller than the tint-free pupillary zone of the lens, giving rise to an imperfect but acceptable cosmetic effect of a heterochromic iris with a large blue outer zone (from the tinted lens) and small hazel inner zone (from the natural iris).

The procedures for fitting tinted lenses may differ from those employed for fitting non-tinted lenses. Tinted rigid lenses need to be of a large diameter so as to cover as much of the cornea as possible and to minimize lens movement. Tinted soft lenses are also best fitted marginally steeper than non-tinted lenses so as to reduce lens movement. A full appreciation of the cosmetic effect of tinted lenses is gained by viewing the lenses in the eyes (using a mirror in the case of the patient) in environments that the patient anticipates being in – that is, both inside under artificial light and outside in natural light.

LENS MAINTENANCE

Chlorine-based disinfecting solutions can cause some lens fading (Brazeau, 1989). All other lens care products appear to be innocuous in this regard, including hydrogen peroxide disinfecting solutions (Janoff, 1988) and alcohol-based daily-cleaning surfactant solutions (Lowther, 1987). Intensive cleaners that employ acids, bases and oxidizing agents could cause tint fading, and so should not be used on tinted lenses.

OXYGEN TRANSMISSIBILITY

Although tinting using laminate construction reduces oxygen transmissibility by increasing lens thickness, the other tint processes described above do not appear to affect lens oxygen performance (Benjamin and Rasmussen, 1986).

VISUAL EFFECTS

Patients who wear opaque lenses with a clear pupil sometimes complain of haze or a veiling effect in their peripheral vision. This is due to a slight restriction of the visual field during the wear of such lenses. The phenomenon is more noticeable if the lens becomes decentred. Spraul et al. (1998) have demonstrated measurable visual impairment when wearing such lenses, and advise against wearing them when driving. Their finding is supported by Albarrán Diego et al. (2001), who showed tinted lenses also affected static perimetry results, but not colour vision (Farnsworth-Munsell 100-hue colour test) or contrast sensitivity (Vistech 6000). Others have found colour-tinted contact lenses are associated with a reduction of contrast sensitivity function (Ozkagnici et al., 2003) owing to an increase in ocular higher-order aberrations (Hiraoka et al., 2009; Takabayashi et al., 2013; Ortiz and Jiménez, 2014; Watanabe et al., 2014; Jung et al., 2015).

OCULAR EFFECTS

Spiteri et al. (2012) reported a case of pigmented corneal iron lines following use of tinted soft contact lenses. A 16-year-old girl was referred with suspected contact-lens-related keratopathy in both eyes, having recently switched to tinted soft monthly disposable contact lenses (8.4/14.0; RE −3.00 OD, LE −3.25; Aquamarine SofLens Natural Colours, Bausch and Lomb, New York, USA). Both corneas exhibited symmetric superficial corneal pigmented iron lines, which gradually disappeared following discontinuation of lens wear. The authors suspected that a poorly fitting tinted lens resulted in localized tear pooling between the lens and cornea and subsequent iron pigment deposition, similar to that seen with orthokeratology.

Kurna et al. (2012) reported the unusual case of a 38-year-old woman who presented to a clinic with a painful red eye and epiphora after having worn hydrogel coloured contact lenses. On biomicroscopy, a large corneal epithelial defect and ring infiltrate were observed. The patient had been using topical anaesthetic drops for 10 days. After cessation of the anaesthetic drops, the corneal lesions resolved completely in 2 weeks. The authors advised that misuse of topical anaesthetics should also be considered when observing a contact lens user with atypical keratitis.

Hau and Tuft (2009) reported a case of presumed corneal argyrosis in a 67-year-old woman who had worn silver-nitrate-coated occlusive soft lenses for 17 years for the management of intractable diplopia. Slit-lamp examination revealed a diffuse blue-grey deposit that was characteristic of corneal argyrosis just anterior to Descemet's membrane. Confocal microscopy showed hyper reflective granules in Bowman layer, deep stroma, and Descemet's membrane. Specular microscopy showed an abnormal reflection from the region of Descemet's membrane. Central corneal endothelial cell density was 2560 cells/mm^2.

Hong et al. (2010) reported a case of corneal deposition of pigments from cosmetic contact lenses after intense pulsed-light therapy. A 30-year-old female visited an outpatient clinic with ocular pain and epiphora in both eyes; these symptoms developed soon after she had undergone facial intense pulsed-light treatment. The patient was wearing cosmetic contact lenses throughout the procedure. At presentation, her uncorrected visual acuity was 2/20 in both eyes, and the slit-lamp examination revealed deposition of the colour pigment of the cosmetic contact lens onto the corneal epithelium. The corneal epithelium was scraped using a number 15 blade; seven days after the procedure, the corneal epithelium had healed without any complications. This case highlights the importance of considering the possibility of ocular complications during intense pulsed-light treatment, particularly in individuals using contact lenses. The authors advised that, to prevent ocular damage, intense pulsed-light procedures should be performed only after removing contact lenses and applying eye shields.

The wearing of tinted lenses containing iron oxide and other metals are contraindicated during magnetic resonance imaging as they are a potential hazard (Kuroda et al., 2014). Tokue et al. (2013) presented a rare case of incidental discovery of tinted contact lenses that showed up in images in a patient wearing such lenses. The authors advised that radiologists, radiographers and referring physicians should be familiar with the imaging findings and potential risk of scanning tinted contact lenses by magnetic resonance imaging.

SAFETY

Concerns regarding the safety of cosmetically tinted contact lenses have been reported in the literature. To investigate this, Rah et al. (2013) evaluated the safety of cosmetically tinted contact lenses in a large number of patients across six clinical trials that varied from 1 week to 3 months in duration. Lenses tested included the Naturelle limbal ring daily disposable, Lacelle limbal ring daily disposable, Lacelle coloured cosmetic daily disposable, Lacelle limbal ring planned replacement at 2 weeks, and Alamode traditional/annual coloured cosmetic lens. The primary safety outcome was slit-lamp examination, including epithelial oedema, epithelial microcysts, corneal staining, bulbar injection, limbal injection, upper lid tarsal conjunctival abnormalities, corneal neovascularization, and corneal infiltrates. High-contrast logMAR visual acuity with lenses and lens-wearing time, movement and centration were also presented.

A total of 871 subjects (1742 eyes) and 23 clinical investigators participated in the six studies, with an average completion rate of 96.4% across all studies. The mean age of the patients was 26.8± 86.6 years, and 86.7% of participants were female. The total number of slit-lamp examinations across the six studies was 2456 visits by eye (1228 visits by patient). There were no slit-lamp signs >grade 2 for any finding, with the exception of corneal staining in one study. In this study, grade 3 corneal staining was noted in one eye (0.1%) at follow-up visit 1 and four (0.6%) of all eligible dispensed eyes at follow-up visit 2, with no eyes requiring medical treatment. No adverse events were reported during any of the trials.

Rah et al. (2013) concluded that cosmetically tinted lenses are safe when properly prescribed by an eyecare professional and used in a compliant manner.

REPLACEMENT FREQUENCY

Tinted lenses are available in daily disposable and reusable modalities. Although a hand-painted prosthetic lens cannot be supplied on a frequent replacement basis, where lenses are fitted for a medical reason they are likely to be worn regularly so should be replaced as frequently as possible. Daily disposable tinted lenses are the most convenient way of avoiding problems of compliance with intermittent use of reusable lenses.

CARE OF MULTIPLE PAIRS

Some fashion-conscious patients may possess numerous pairs of lenses of different tint designs. Such patients should be advised to mark their lens cases to avoid repeated opening, thus reducing the risk of contaminating stored lenses. Advice should be given to the patient concerning long-term lens storage, such as the desirability of periodic lens cleaning even if the lenses have not been worn.

LENS DEPOSITS

Although disposable tinted lenses are available, some products, such as theatric lenses, are more expensive and are retained for long periods of time. Long-term lens maintenance therefore becomes an important issue. Some tinting processes can alter the lens surface charge. This could facilitate increased protein deposition (Lowther, 1987), the consequences of which may be decreased vision and comfort, sensations of dryness, susceptibility to adverse eye reactions, lens distortion and alterations to lens fitting characteristics.

DISCOMFORT AND DRYNESS

Tinting processes can alter lens surface chemistry, which in turn can reduce surface wettability and lead to symptoms of dryness (Daniels and Mariscotti, 1989). Slight irregularities caused by surface tints may render tinted lenses slightly less comfortable than equivalent non-tinted lenses (Steffen and Barr, 1993). Ocular lubricants can help alleviate these sensations.

Conclusion

The utility of contact lenses has been extended considerably as the result of the development of innovative tinting procedures, so that almost any desired effect can be achieved. Tinted lenses therefore constitute an important vehicle for satisfying the cosmetic, prosthetic, therapeutic and prophylactic needs of patients.

Access the complete references list online at http://www.expertconsult.com.

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23

Presbyopia

JOHN MEYLER | DAVID RUSTON

Introduction

An area that historically has been perceived as being particularly challenging within contact lens practice is fitting presbyopic patients with contact lenses so as to allow them to fulfil the majority of their visual requirements. However, the availability of newer optical designs, daily disposability and lens designs in enhanced hydrogel, silicone hydrogel and high-permeability rigid lens materials means there is less restriction to the modality of wear or physiological compromise when attempting to correct presbyopia with contact lenses and that the visual outcomes are significantly better than previously. This has resulted in a higher rate of prescribing by practitioners of contact lenses for presbyopic patients (Fig. 23.1) (Morgan et al., 2016). Notwithstanding this increased prescribing, the penetration of contact lenses falls away dramatically in the over-45-year-old age group – a demographic for which the need for a presbyopic correction doubles (Fig. 23.2). To obviate this necessitates a keen interest in meeting the visual and physiological needs of this very important patient group.

With the presbyopic population growing in size at an ever-increasing rate along with the pre-presbyopic, practitioners can expect to see a rise in the number of presbyopic patients attending for this form of lens fitting. Offering contact lens correction to this group should now be considered as an integral, routine part of contact lens practice and represents a very significant opportunity for practice growth and increased patient satisfaction.

The options for the correction of presbyopia to both existing and new contact lens wearers include:

- distance-powered contact lenses and near-reading spectacles
- bifocal or multifocal contact lenses:
    - simultaneous image contact lenses
    - alternating image contact lenses
- monovision.

The contact lens options for presbyopic correction are shown in Fig. 23.3 with some examples of the different brands available.

Each option has advantages and disadvantages, which vary with the lens type, the fitting approach used and the degree of presbyopia present. A systematic approach to lens selection can be used depending on the stage of presbyopia, as shown in Box 23.1 (Christie and Beertren, 2007).

Distance-powered contact lenses combined with near-reading spectacles may be the simplest and least expensive option. However, it does not address the problem for the patient who does not wish to wear spectacles, and it may even demotivate an existing lens wearer. Many contact lenses wearers becoming presbyopic want to continue to wear contact lenses as their primary correction option for their vision correction needs and not being given this option is a very significant reason for ceasing contact lens wear. It should be remembered that

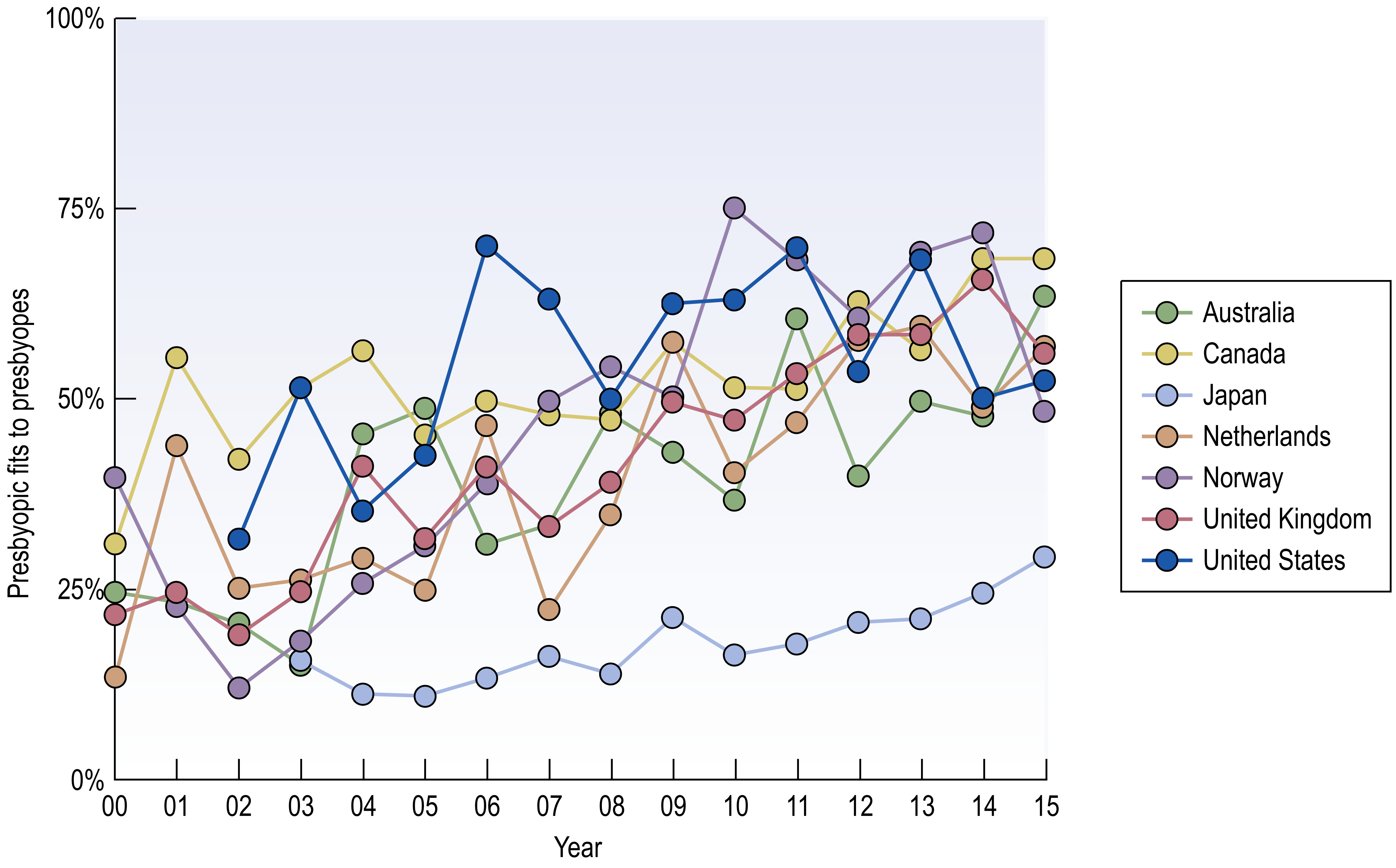


Fig. 23.1 Multifocal and monovision contact lens fits as a proportion of all soft lens fits to presbyopes (those over 45 years of age) in seven nations between 2000 and 2015.

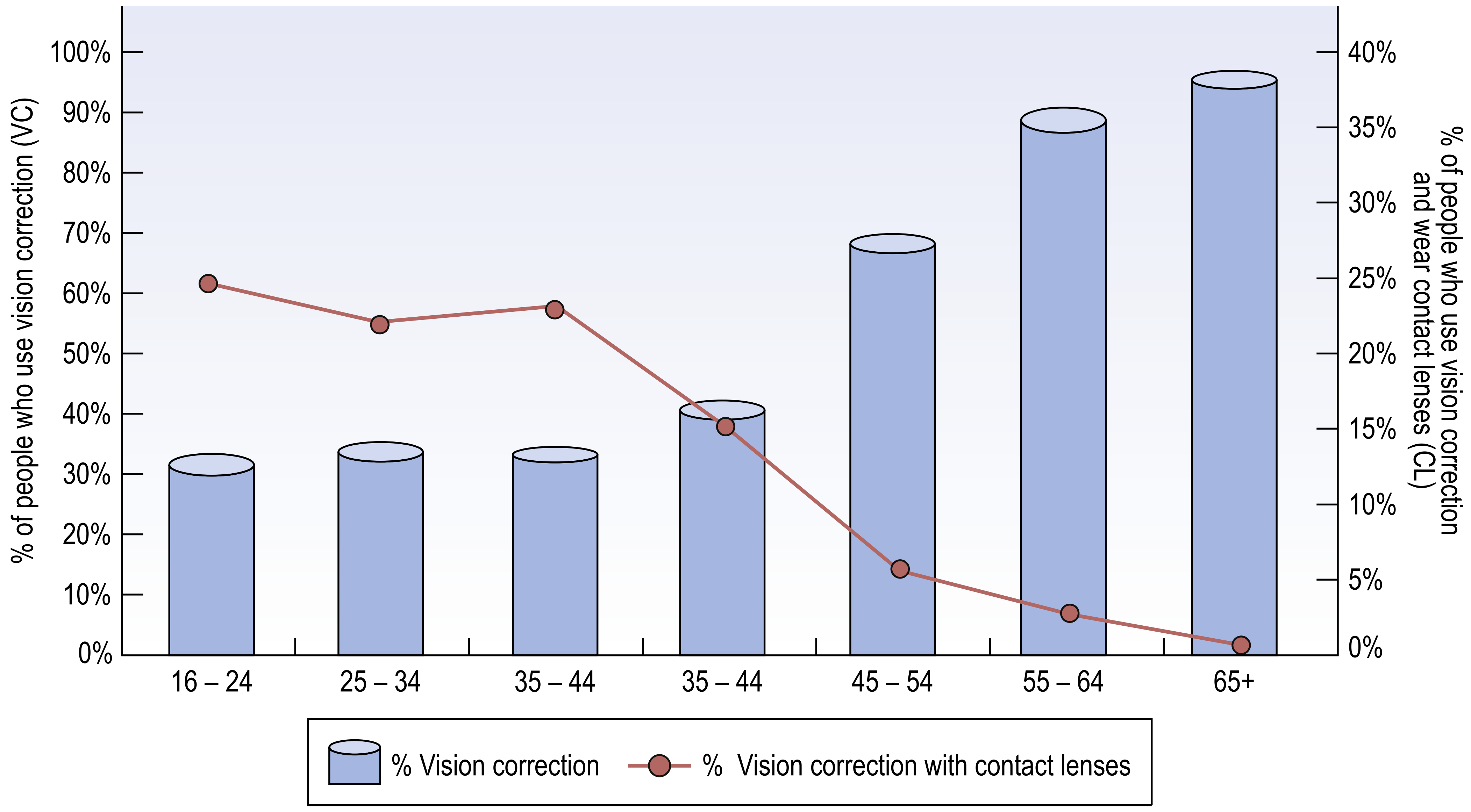


Fig. 23.2 Comparison of the percentage of patients wearing vision correction across the age range versus the proportion wearing contact lenses. (Adapted from VisionTrak Data 2007; includes data from the UK, France, Germany and Italy.)

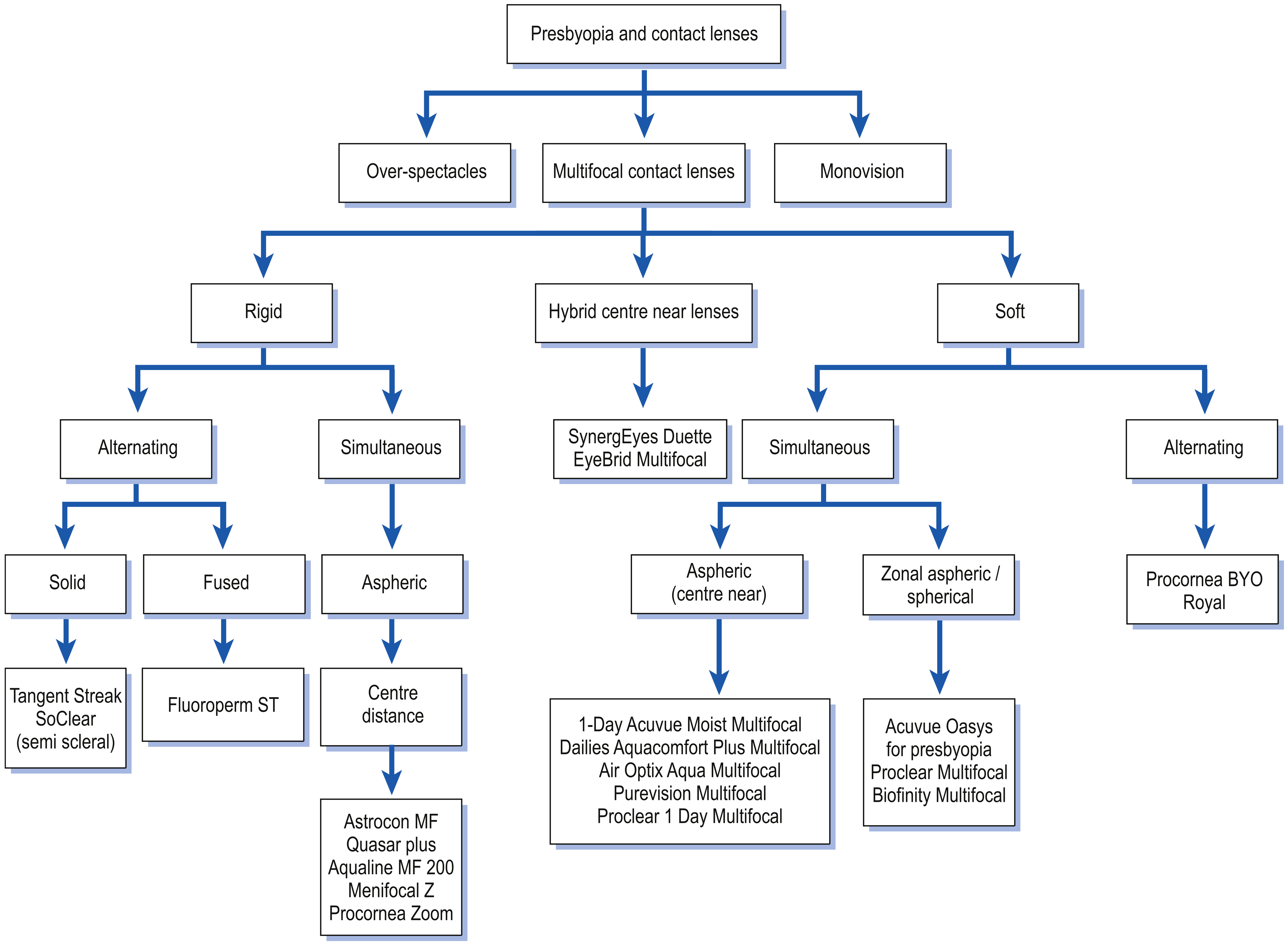

Presbyopia and contact lenses
Over-spectacles
Multifocal contact lenses
Monovision
Rigid
Hybrid centre near lenses
Soft
Alternating
Simultaneous
SynergEyes Duette
EyeBrid Multifocal
Simultaneous
Alternating
Solid
Fused
Aspheric
Aspheric (centre near)
Zonal aspheric / spherical
Procornea BYO Royal
Tangent Streak
SoClear
(semi scleral)
Fluoroperm ST
Centre distance
1-Day Acuvue Moist Multifocal
Dailies Aquacomfort Plus Multifocal
Air Optix Aqua Multifocal
Purevision Multifocal
Proclear 1 Day Multifocal
Acuvue Oasys for presbyopia
Proclear Multifocal
Biofinity Multifocal
Astrocon MF
Quasar plus
Aqualine MF 200
Menifocal Z
Procornea Zoom

Fig. 23.3 Contact lens options for presbyopia correction with some examples of various brands.

BOX 23.1 FITTING APPROACH DEPENDING ON DEGREE OF PRESBYOPIA

EMERGING PRESBYOPE (UP TO +1.00 D)

- Simultaneous: full correction in both eyes
- Monovision: distance and full near

MID-PRESBYOPE (+1.25 TO +2.00 D)

- Simultaneous: full correction to both eyes
- Translating: full correction to both eyes (do not overcorrect add)
- Monovision: distance and full near

LATE PRESBYOPE (+2.25 TO +3.00 D)

- Simultaneous: modified monovision; enhanced monovision
- Translating: full correction to both eyes
- Monovision: distance and partial near; consider top-up spectacles to provide additional plus

(Adapted from Christie & Beertren, 2007.)

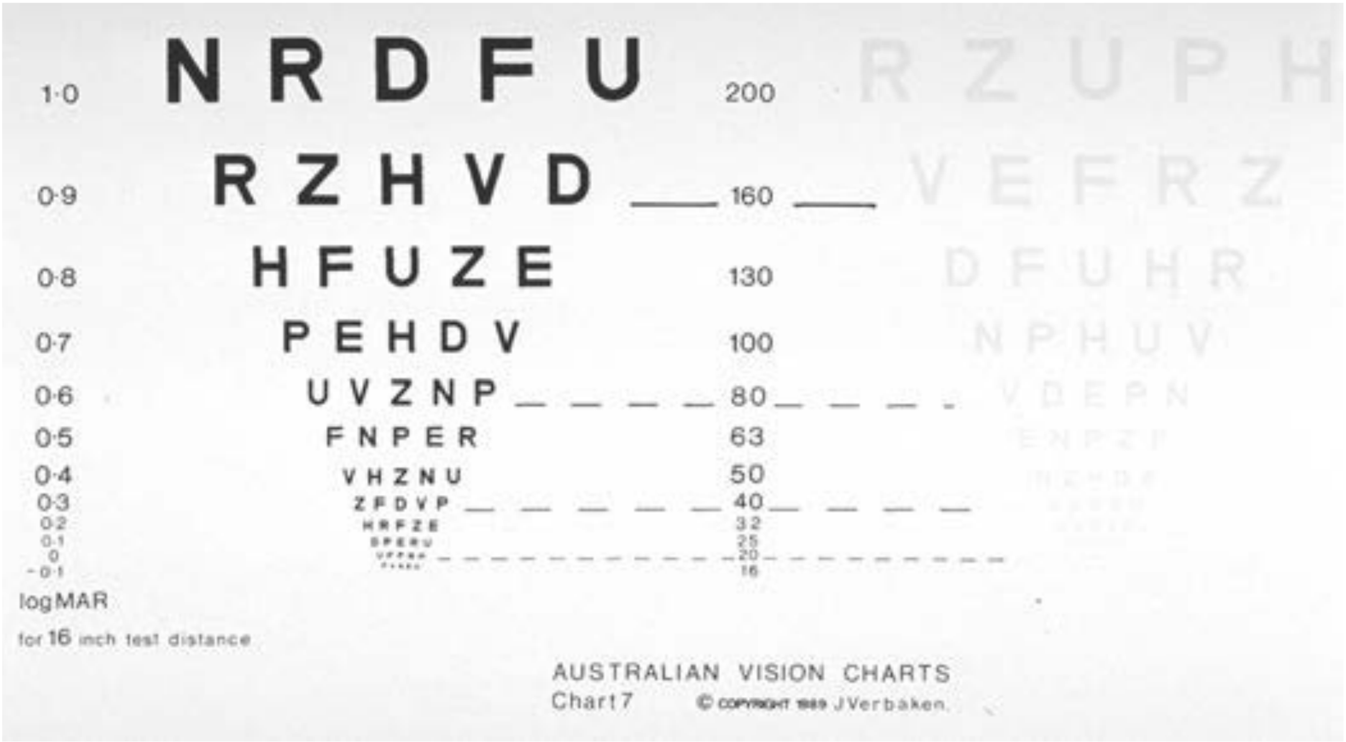


Fig. 23.4 High- and low-contrast visual acuity chart. (Modified from Bennett, E. S. (2007). Bifocal and multifocal contact lenses. In A. J. Phillips and L. Speedwell (eds) Contact Lenses (5th ed., pp. 311–331). Oxford: Butterworth-Heinemann.)

intermittent use of spectacles is often far more inconvenient than constant use.

Patient Selection

Patient motivation plays an important role in any form of contact lens fitting. However, this motivation is often restricted to those patients who are aware of the various contact lens options, which they are then keen to explore further. Perhaps more important is informed choice based on the advantages and disadvantages of the various options available, as the majority of patients are not aware that contact lenses are a possibility for the correction of presbyopia. This more 'proactive' approach may result in somewhat lower success rates but, inevitably, a larger contact lens patient base. Back et al. (1989) have shown that a significant proportion of an unselected presbyopic population can achieve success with simultaneous image multifocal contact lenses.

Caution should prevail when considering patients with compromised binocular vision, amblyopia, distance acuity of less than 6/12 or exacting critical vision needs for either distance or near vision. High- and low-contrast visual acuity charts (Fig. 23.4) give more information about acuity. In particular, the difference in low-contrast acuity between spectacles and contact lenses may give some indication of possible success.

It is more important, however, to have access to trial lenses to obtain an idea of potential success for any particular type of multifocal lens or fitting technique based on both patient subjective feedback and objective measurement. As with any contact lens preassessment, careful attention should be paid to tear quality and quantity, which are often reduced in this age group, as well as eyelid tone and position. Selection of a lens material that offers high wettability and low coefficient of friction may be especially relevant in the presbyopic age group. When commencing this form of lens fitting, it may help to start with selecting patients that are generally accepted as being 'better' candidates rather than choosing those who might be considered as 'more challenging' to fit successfully. Table 23.1 summarizes the different patient types when considering fitting simultaneous image, alternating image and monovision (Bennett, 2007).

PATIENT EXPECTATIONS

It is important that patients are given realistic expectations about the likely level of vision, as with any type of vision correction for presbyopia. It is necessary to ensure that patients fully understand the basis of presbyopia and their expectations should be set out in a positive but informative manner. This involves discussing the benefits of combined distance/near correction without the need for spectacles (less head movement, no peripheral distortion, more natural image formation) as well as likely differences between the visual performance of monovision, simultaneous image or alternating image lenses. When compared with spectacles or single-vision contact lenses, visual decrements may be noticed, such as reductions in visual acuity (especially in low luminance) and possibly stereopsis, and reduced intermediate vision depending on the type of lens fitted. It should also be explained to the patient that it is quite normal for fitting to require more than one appointment in order to try out alternative lens powers and fitting approaches, depending on their assessment of lens performance in their everyday visual environment.

Initial Measurements

Measurement of the ocular dominance or sighting preference is useful in establishing which eye to correct for distance vision during monovision fitting, or while making adjustments during simultaneous lens fitting. Ocular dominance can be determined using preferential looking tests or alternatively by the +1.00 D sensory test. The former is carried out by sitting opposite the patient and asking the patient to look through a hole in a piece of card at an open eye of the practitioner. Whichever eye the patient lines up with the open eye of the practitioner is the dominant one. The latter test involves placing the best binocular distance refraction in the trial frame and, while patients look at the lowest line they can read, a +1.00 D lens is placed alternatively in front of each eye. Patients indicate when the vision is clearest, viewing the distance chart. If the +1.00 D lens is in front of the left eye when the image is reported as clearest, then the right eye is considered as distance dominant, and vice versa. It has been found that unsuccessful wearers became successful after switching near and distance corrections contrary to the dominance as measured by traditional methods, but rarely contrary to the +1.00 D sensory test (Michaud et al., 1995). Nowadays most manufacturers recommend the +1.00D sensory test to assess dominance. Historically, pupil size measurements were useful when fitting biconcentric designs; however, this procedure is less relevant with more recent designs. Nevertheless, larger

TABLE 23.1 Patient Selection for Presbyopic Contact Lens Correction

	Patient Selection		
	Simultaneous	Alternating	Monovision
Good candidates (getting started)	Existing soft lens wearers who are emerging presbyopes Moderate intermediate-vision requirements Spherical or near-spherical refractive errors Willing to accept some limited compromise in distance vision	Moderate and advanced presbyopes Lower lid above, tangent to, or no more than 1 mm below the limbus Myopic or low hyperopic powers Normal to large palpebral apertures Normal to tight lid tension	Significant astigmatic refractive error Reading positions other than standard downward gaze Current contact lens wearers Motivated and realistic expectations
More challenging candidates (experience required)	Do not desire any compromise in distance vision Emmetropic or near-emmetropic distance refractive error Would benefit from a toric correction Small pupil size (<3 mm)	High hyperopes Small palpebral apertures Loose lower lids	Low myopes Concentrated specific visual needs High reading addition High visual demands and expectations

(Modified from Bennett, E. S. (2007). Bifocal and multifocal contact lenses. In A. J. Phillips and L. Speedwell (eds) Contact Lenses (5th ed., pp. 311–331). Oxford: Butterworth-Heinemann.)

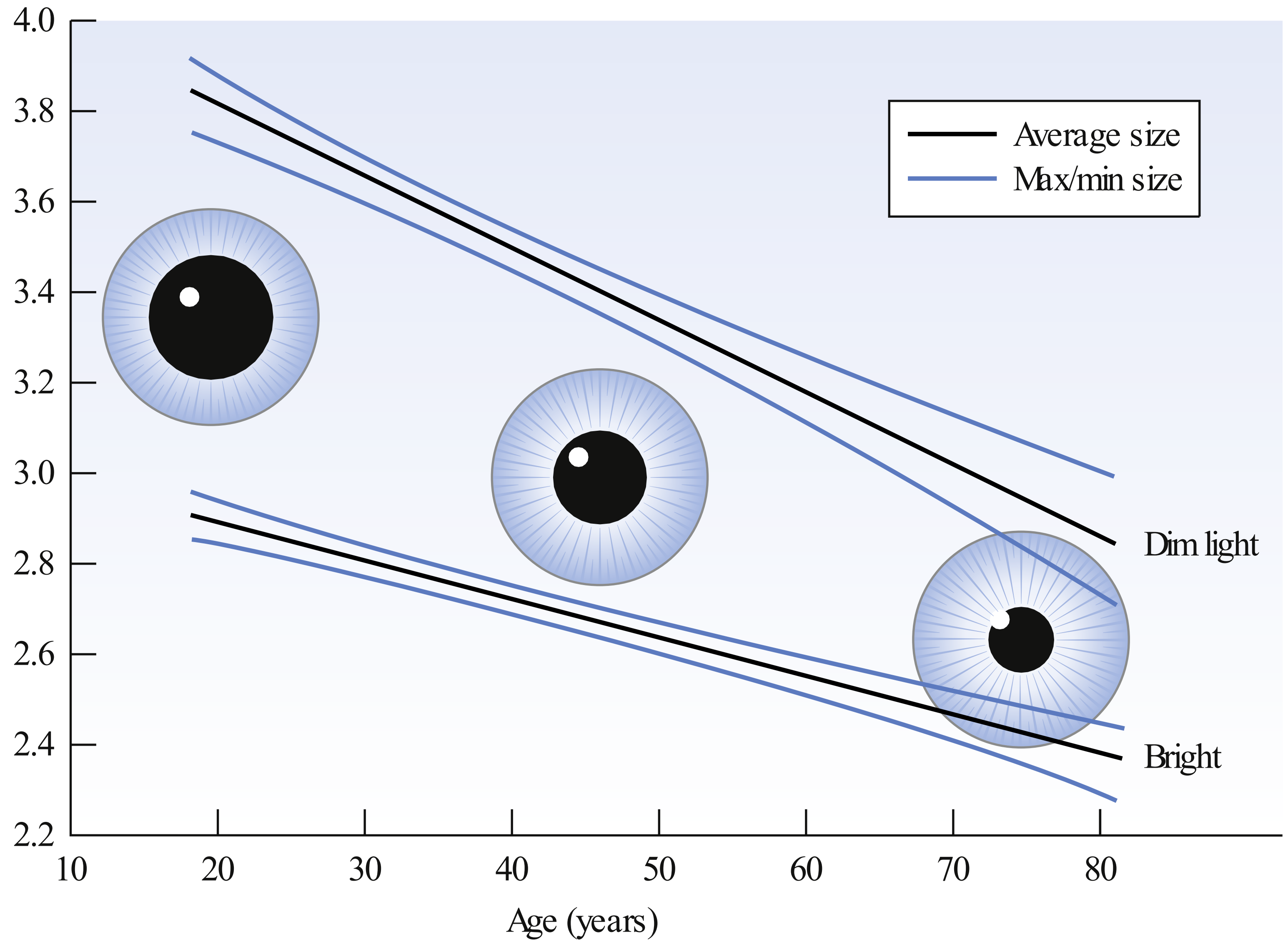


Fig. 23.5 Variation of pupil size at two luminance levels with age. (Adapted from Dumbleton et al. (2015).)

pupils can be more challenging when fitting alternating image lenses and very small pupils may be less successful when fitting simultaneous image lenses.

Pupil Size

Pupil size is known to decrease with age, as well as when looking at near objects and, of course, under photopic conditions (Fig. 23.5). If a centre-near multifocal contact lens design is not optimized and has a fixed design for all reading additions, visual performance can be reduced as the pupil size diminishes with age. Most, but not all, current multifocal designs (Fig. 23.6) are adapted to reflect this age change as the reading addition increases assuming that higher reading adds will be required for older patients.

A more recent finding is that not only does pupil size vary with age but also that refractive error can influence pupil size, with myopes tending to have larger pupil size than hyperopes, particularly in mesopic light conditions (Cakmak et al., 2010) (Fig. 23.7). A study by Dumbleton et al. (2015) has recently confirmed this finding and discussed the implications for multifocal design.

Although these pupil size differences may be relatively small, when considered as an area this can have a significant impact on visual performance. Dumbleton's data indicates that the difference in pupil size area from a −8.00 D myope to a +6.00 D hyperope is 24%. If not considered in the lens design, this can result in differences in success between myopes and hyperopes. A more recent lens design (Fig. 23.8) varies the optic profile both across the prescription and the reading addition range so as to optimize optics and visual performance.

Bifocal and Multifocal Contact Lenses

Bifocal and multifocal contact lenses can be simultaneous or alternating image designs. Simultaneous designs generally

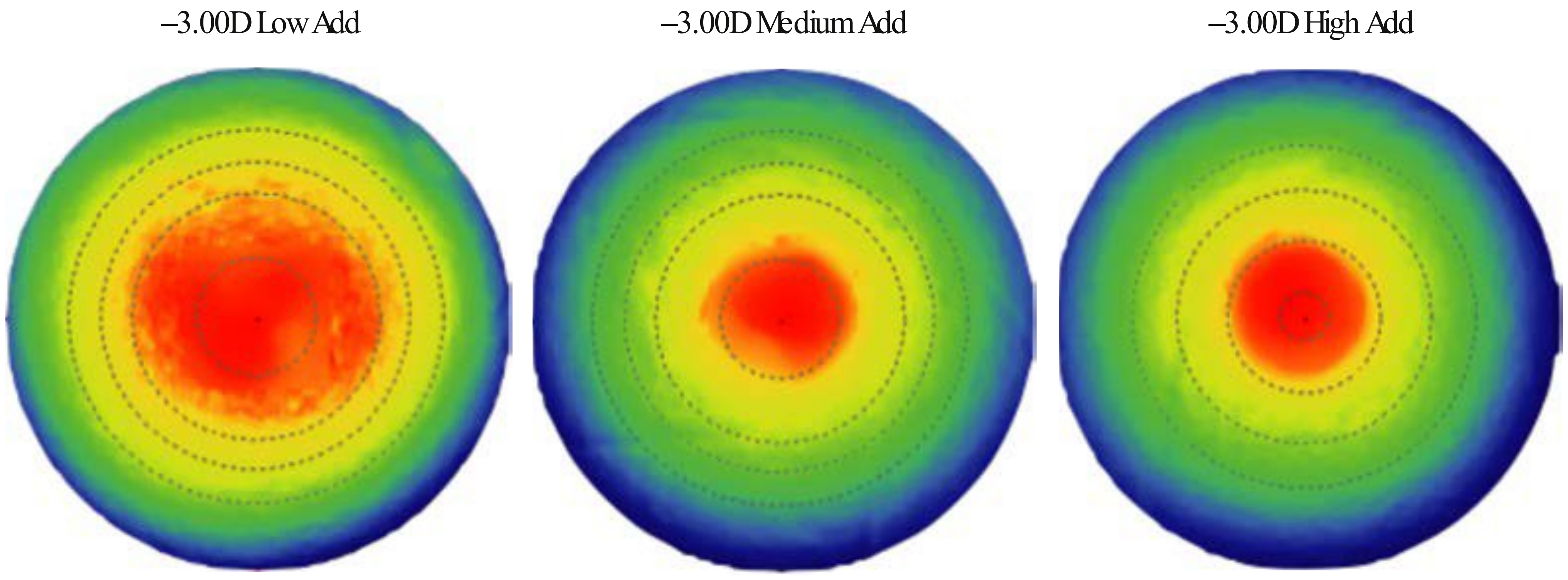


Fig. 23.6 Dioptric power maps of three different reading additions having the same distance power in a centre-near multifocal lens design. It can be seen that the power distribution falls away more rapidly as the add increases. (Red indicates higher powers; blue indicates lower powers.)

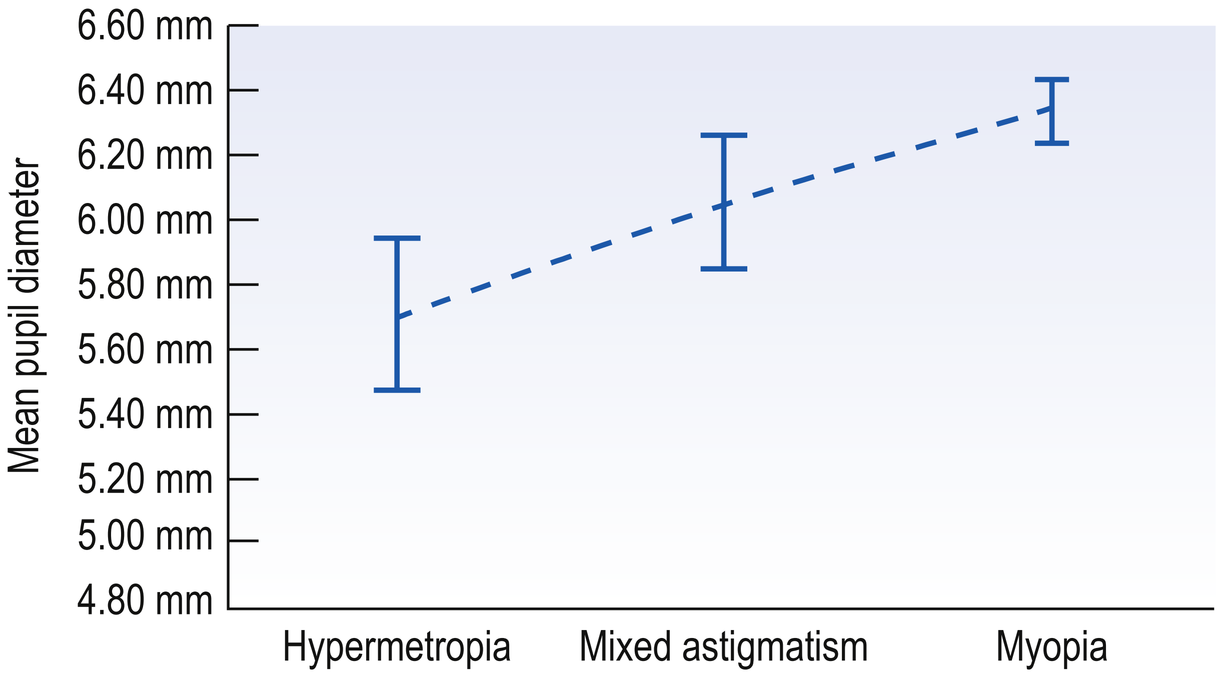


Fig. 23.7 Variation of pupil size with refractive error in mesopic conditions. (From Cakmak, H. B., Caqil, N., Simavli, H. et al. (2010). Refractive error may influence mesopic pupil size. Curr. Eye. Res., 35, 130–136.)

require the lens to be relatively stable on the eye and will be associated with some form of visual compromise because objects at both distance and near are imaged simultaneously on the retina. Alternating image lenses require significant lens movement so that the distance and near portions of the lens can be positioned over the pupil by interaction with the lids.

Comparative studies have concluded that multifocal contact lenses perform better, in many different forms of visual measurements, than monovision correction (Rajagopalan et al., 2006; Richdale et al., 2006; Bennett, 2008; Gupta et al., 2009; Woods et al., 2009. However, Chu et al. (2009) reported that multifocal contact lens wearers were significantly less satisfied with aspects of their vision during night-time driving compared with daytime driving, particularly regarding disturbances from glare and haloes.

HISTORICAL DESIGNS

Early soft and rigid simultaneous image lenses were biconcentric in design, consisting of two discrete zones of distance and near power. A centre-distance design has the central portion of the optical zone for distance vision, which is surrounded by an area containing the near power. In centre-near designs, the optical principle is the same as for the centre-distance lens, although reversed so that the central portion of the lens focuses the light from close objects and this is surrounded by a distance-powered area. Visual performance with both these designs was significantly impacted by their dependency on pupil size. Biconcentric designs in both soft and rigid materials are still available but are now rarely used owing to the availability of more advanced, easier-to-fit designs and single-use disposable lenses. Diffractive bifocal contact lenses used refraction to correct distance vision and a combination of refraction and diffraction to correct near vision. Diffractive lenses were largely independent of pupil size (Young et al., 1990); however, like aspheric designs, they were dependent on lens centration. Image formation is achieved by a diffractive 'zone plate' on the back surface of the lens, which is able to split the incident light passing through into two discrete focal points. Approximately 20% of incident light is lost to higher orders of diffraction, leaving 40% of light to make up each image (Benjamin and Borish, 1994), which explained the greater reduction in low-contrast acuities with such lenses when compared with monovision correction (Harris et al., 1992). Diffractive contact lenses are no longer available, but diffractive optics continues to be used in bifocal intraocular implants.

Another approach to reduce the dependency of lens function on pupil size especially in different lighting conditions was to increase the number of concentric zones, and to power these zones alternatively for distance and near vision. This approach was adopted in a centre-distance multizone design consisting of five alternating distance and near-powered zones (Meyler and Veys, 1999).

The multiple-ring configuration is designed to provide vision that is more specific to the available lighting conditions.

SIMULTANEOUS IMAGE DESIGNS

A variety of simultaneous lens designs are available in both rigid and soft materials. The availability of single-use disposable soft trial lenses and empirically ordered individually based aspheric rigid lenses has resulted in an increased prescribing of this form of lens correction; it has approximately doubled in the last 10 years (Morgan et al., 2016).

In simultaneous image designs, the distance, intermediate and near correction zones are both positioned in front of the pupil in every direction of gaze so that light from either a distant or near object passes through all zones. As fixation is directed to either a distant or a near object, one zone produces a focused image while the others produce a blurred image that overlaps the same retinal elements as the focused one (Benjamin and Borish, 1994) (Fig. 23.9).

The placing of simultaneous images on the retina by any optical system relies on the visual system being able to select the clearer picture and to ignore the out-of-focus image, whether a distant or near object is being viewed. The phenomenon of binocular summation improves the end result by improving on

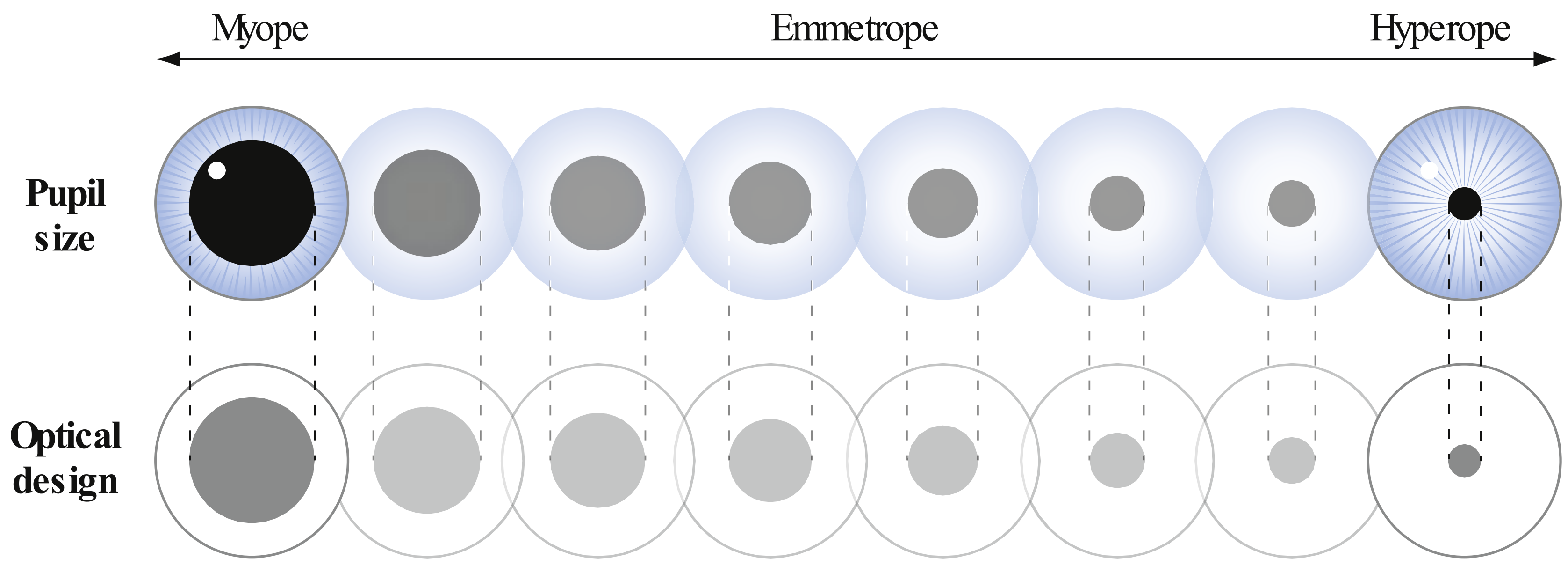


Fig. 23.8 Schematic showing how the pupil size varies across the refractive range and how one manufacturer has optimized the optical design for each individual lens parameter to reflect this.

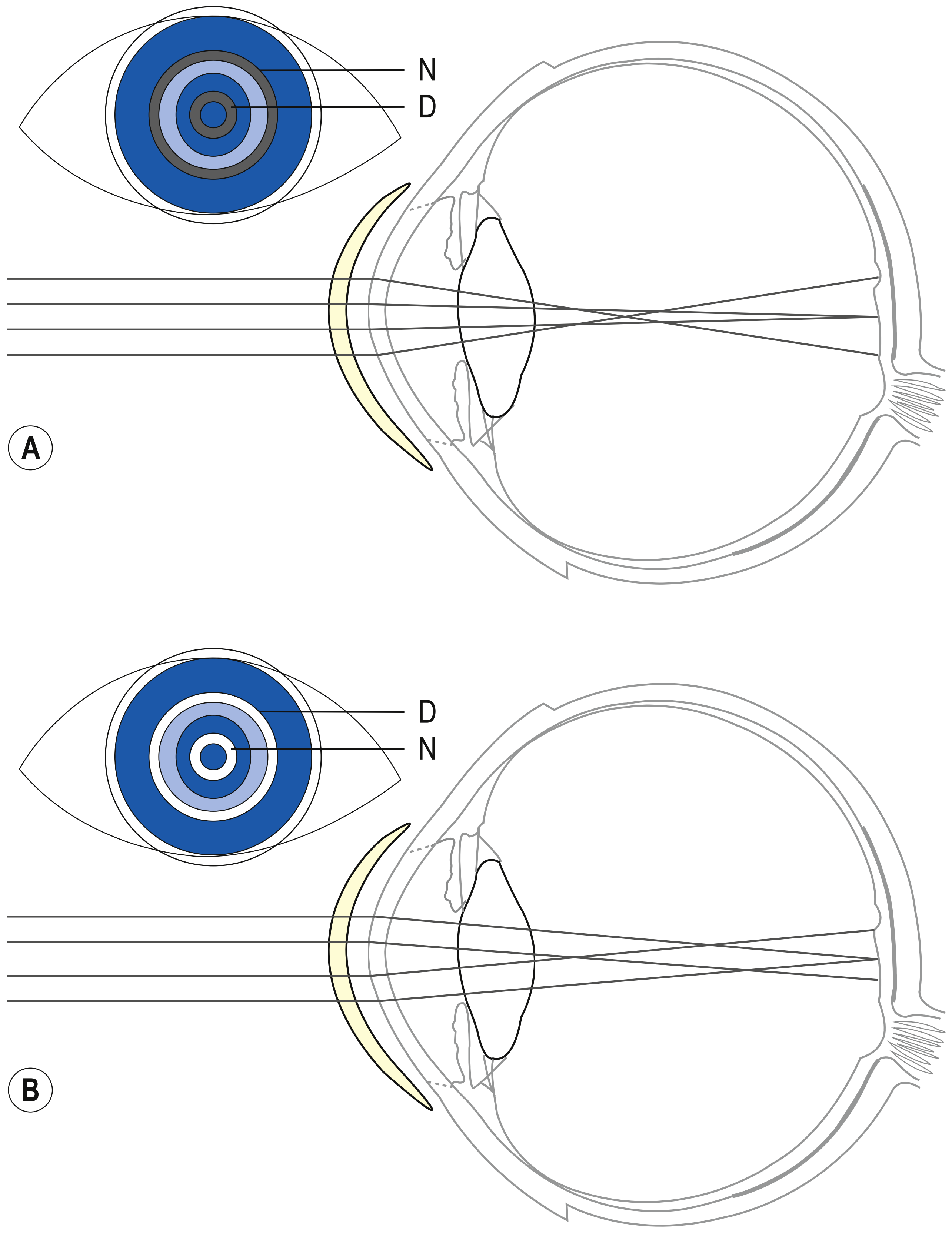


Fig. 23.9 Principle of simultaneous vision design. (A) Centre-distance design. (B) Centre-near design. D = distance; N = near.

the monocular images and generating a binocular image that offers improved contrast and acuity. Care needs to be exerted to remain in the zone of summation versus extending into the zone of inhibition. Summation is thought to occur when the amount of optical disparity is less than 1.00 D.

The spread of light from the defocused image reduces the contrast of the focused image (Borish, 1988). As a result, the fitting of a simultaneous image lens is likely to result in some level of reduction in image quality in comparison with that resulting from a single-vision correction. The extent of contrast loss will depend upon the relative amounts of in-focus to out-of-focus light striking the retina. If equal contrast is to be achieved for both near and far viewing, the refractive system should allow approximate equality of the areas of the two portions of the lens transmitting to the pupil. Lens performance may be affected by many factors, which include pupil size, lens design and centration of optics relative to the pupil. If the optics are decentred with regard to the visual axis then 'shadowing' effects are produced by virtue of induced asymmetrical aberration, principally coma (Charman, 2014). The theoretical retinal intensity of different lens designs and the effect of variations in pupil size can be investigated by measuring their modular transfer function (Young et al., 1990).

Regardless of the different optical principles and designs available, large well-controlled independent studies are required to determine whether patient acceptance is more successful with any one design. Comparing patient acceptance success rates from different studies is difficult owing to differences in success criteria, patient profile and length of study. A study by Situ et al. (2003) showed that existing successful monovision wearers could be successfully fitted with bifocal contact lenses and that after a 6-month period 68% preferred bifocal lenses, compared with a 25% preference for monovision.

Aspheric Designs

With aspheric designs the refractive power gradually changes from the geometric centre of the lens to the more peripheral area of the optic zone. Such lenses are best described as 'multifocal' or "stretch focus" owing to the progression of powers, but can also be considered as a type of concentric design as the power distributions are concentric around the centre of the lens. By the nature of their design, lens function will vary somewhat with changes in pupil size. This can lead to variations in distance- and near-vision image contrast, which can be minimized if the lens design takes pupil size variation into account.

Power distribution is produced by the use of a continuous aspheric surface of fixed, or more typically, variable eccentricity. Aspheric lens designs can be subdivided according to whether the power distribution is most plus (least minus) centrally, resulting in a centre-near design (Fig. 23.10A), or most minus (least plus) centrally resulting in a centre-distance design (Fig. 23.10B). Although both options are available in soft and rigid materials, centre-near front-surface aspheric designs are much more prevalent amongst soft modern aspheric multifocals.

Front-surface Aspheric Designs. Front-surface soft aspheric designs generate negative spherical aberration, resulting in decreasing plus power from the geometric centre of the lens. This in essence creates a centre-near design. The aspheric curve is calculated to increase the overall spherical aberrations of the eye and, if necessary, of the lens itself. The increase in depth of focus can be effective at correcting the early presbyopic patient (up to +1.50 D). As presbyopia increases, the front-surface curve must have a greater degree of asphericity to allow more plus refractive power within the overall optical system.

This often involves more complex surface geometry of varying eccentricity to allow stabilized distance and near power zones within a specified area.

Apart from the visual demands of the presbyopic patient, it would also be expected that visual performance would depend upon the interaction of the optical characteristics of the particular lens design with the aberrations of the eyes of the wearer. Ocular spherical aberration is unique to the individual. Consequently, variations in ocular aberration between patients may explain in part why lenses of this type meet the needs of some wearers but sometimes not others (Plakitsi and Charman, 1995).

Eyes with greater positive spherical aberration effectively work against negative spherical aberration generated by a centre-near aspheric design resulting in less multifocal add effect. Although the patient may demonstrate improved intermediate acuity, they may require a higher reading add than their spectacle add to improve their near vision effectively. Different centre-near aspheric soft lenses do have different distributions of optical power on their surfaces (Fig. 23.11) and thus it may be possible to improve performance by changing to a different design.

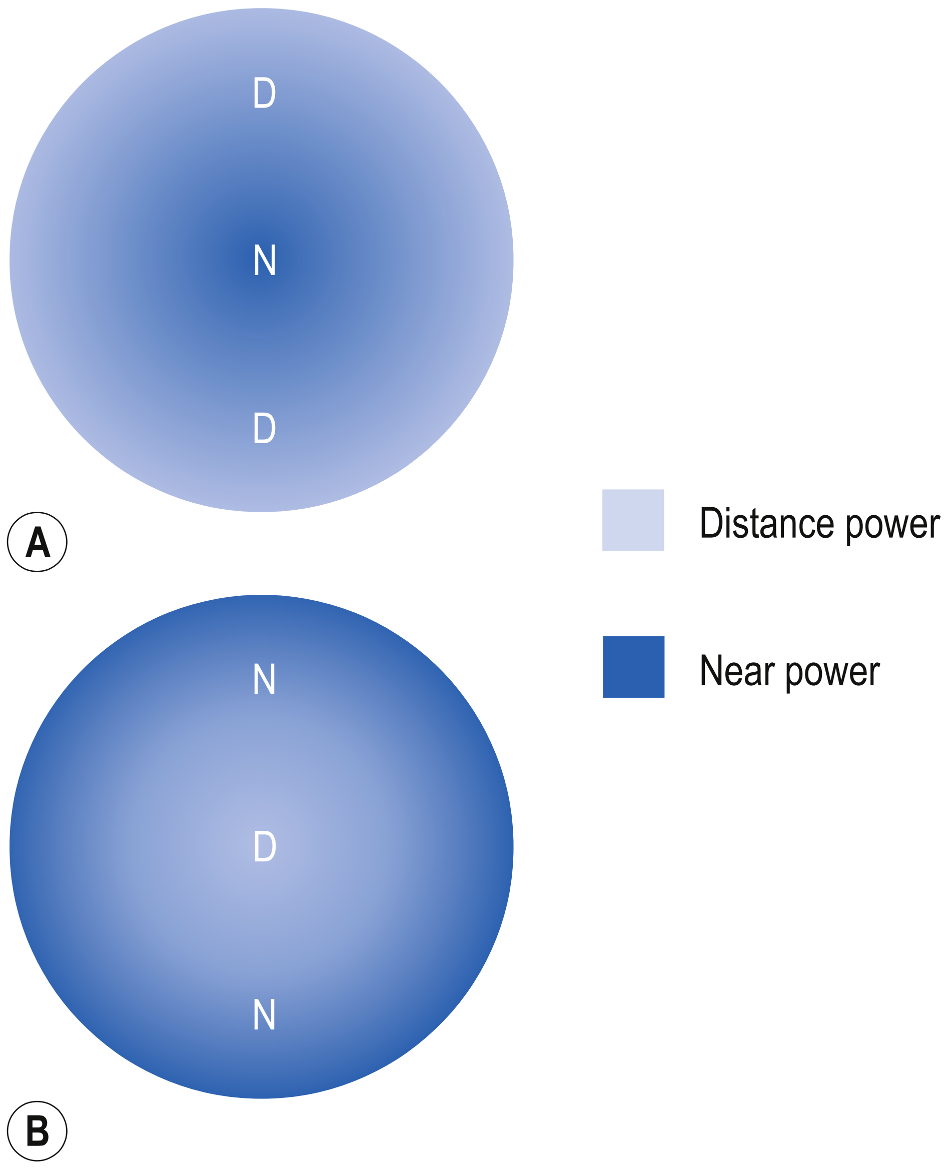


Fig. 23.10 (A) Front surface aspheric centre-near design. (B) Back surface aspheric centre-distance design.

The optical performance and patient satisfaction with front-surface aspheric simultaneous image soft lenses has improved significantly in recent years and they form a very significant part of the recent growth of presbyopic contact lens correction with multifocals (see Fig. 23.1).

Back-surface Aspheric Designs. Back-surface aspheric surfaces that generate the reading addition are mostly found in rigid lens designs and result in power changes from the central distance correction to that required for near vision by inducing positive spherical aberration. The greater the eccentricity (or rate of flattening), the higher is the reading power in relation to distance power. However, the higher the reading addition, the more likely it is that distance vision will be affected adversely, especially in low-contrast and/or low-light conditions. Back-surface centre-distance aspheric soft lenses designs are limited in the amount of positive spherical aberration they can generate and are therefore suitable only for early presbyopia of up to +1.25 D.

However in rigid lenses the back-surface geometry may depart significantly from corneal topography with the 'higher-eccentricity' designs. This is due to rapidly flattening back-surface aspheric geometry. Such lenses will need to be fitted fairly steep to allow for appropriate lens centration (Edwards, 2000). Back-surface aspheric rigid lens designs can now be based on corneal topography and ocular prescription to create an individual lens design for correcting presbyopia (Woods et al., 1999). The aim is to modify the combined optical system of the lens, tears and cornea to provide a predictable varifocal effect.

Zonal Aspheric and Spherical Designs. This approach is designed to allow balanced vision at all distances and synergistically combines the benefits of historical multizone spherical and aspheric soft lens designs. The resulting lens has a zonal aspheric front surface designed to leverage the eyes' natural depth of clear focus. It is available with a range of reading additions. The power profile and zone distribution for each of the add powers have been optimized for the normal

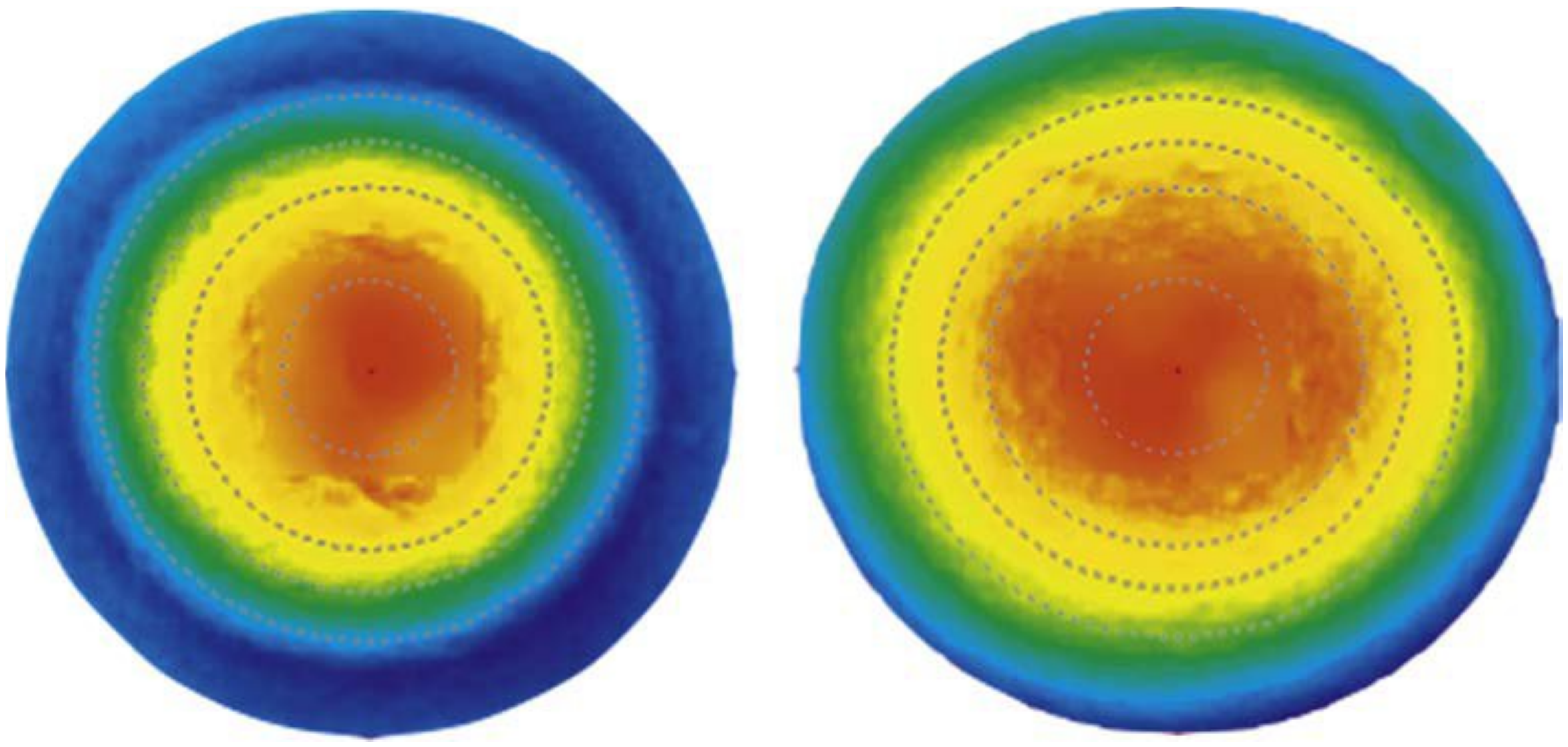


Fig. 23.11 Dioptric power maps of two leading centre-near aspheric simultaneous image contact lenses of similar prescription. Both lenses are −3.00 D with a low add. (Red indicates higher powers; blue indicates lower powers.)

physiological change in pupil size with age as well as illumination changes (Fig. 23.12).

Another approach with zonal designs is to use modified monovision approach with the first pair of lenses trialled. The lens used for the dominant eye is a centre-distance lens design whereas the lens for the other eye is centre-near in design. Lens designs can use aspheric surfaces, spherical surfaces or a combination of both with unique zone sizes to produce two complementary but inverse geometry lenses (Fig. 23.13). Each lens is a multifocal and the intention is that some binocular summation will still occur, with the intention of providing acceptable vision at all distances under binocular conditions. Both centre-near and centre-distance designs have fixed optical zones regardless of add power (Fig. 23.14). This could have the effect of biasing the optical performance towards pure monovision in older wearers. Once again caution is needed to not exceed the level of disparity to cause inhibition.

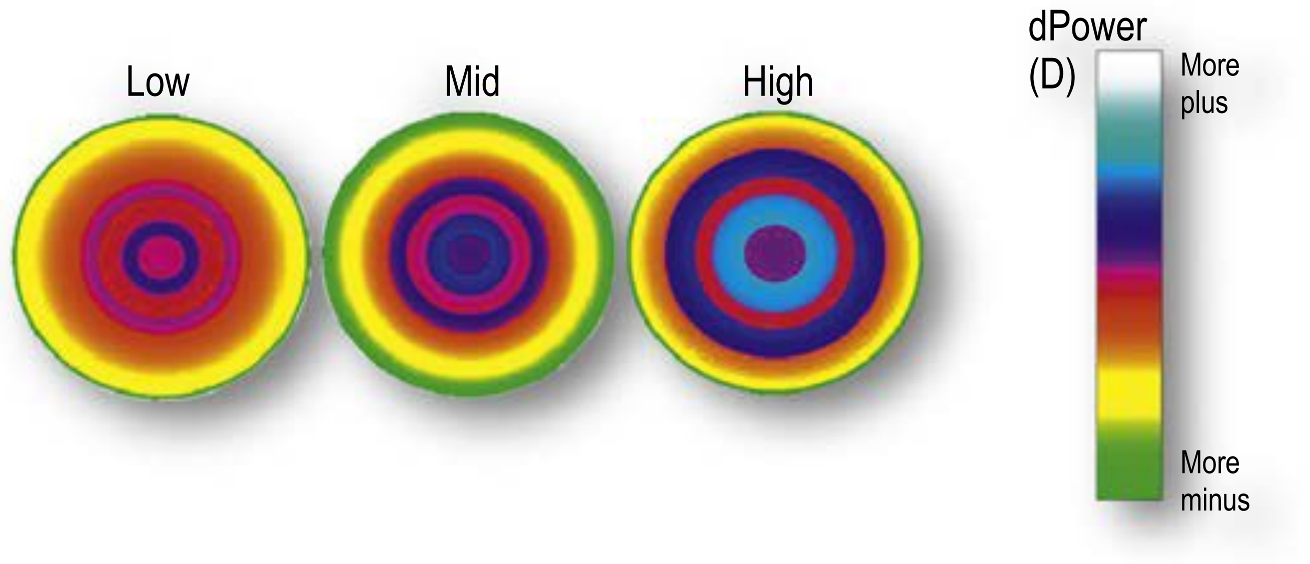
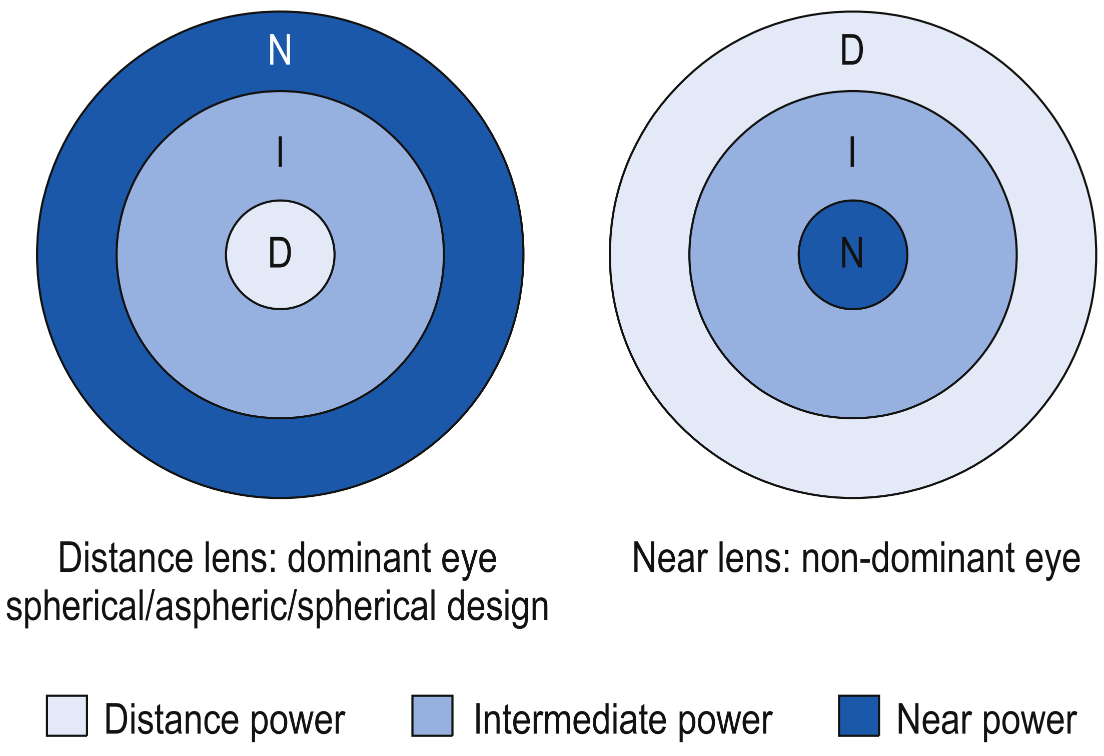


Fig. 23.12 Zonal aspheric design.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Distance lens: dominant eye spherical/aspheric/spherical design
Near lens: non-dominant eye
Distance power
Intermediate power
Near power

Fig. 23.13 Multizone concentric modified monovision design.

Hybrid and Semiscleral Lens Designs

Recent introductions in the practitioner's fitting armoury are hybrid simultaneous image multifocals and semiscleral rigid multifocal lenses. The hybrids have rigid lens centres with silicone hydrogel soft skirts. The semiscleral lenses and hybrids typically have diameters similar to soft lenses. Optically they both have similar designs to soft multifocals, but with the added advantage of correction of corneal astigmatism by virtue of the tear film trapped behind the back surface of the lens. Fig. 23.15 shows the fluorescein pattern of a well-fitted hybrid lens and Fig. 23.16 a semiscleral rigid lens. Problem-solving vision issues with these lenses is similar to that of soft simultaneous-image multifocals.

Lens Fitting

Initial lens power selection and optimal adjustments will vary with each individual lens type; however, the distance power of the multifocal lens will most often be based on the vertex distance-corrected best sphere prescription. This is best derived by placing the calculated best vision sphere in a trial frame and adding positive power until the patient begins to notice a decline in the distance acuity. When vertex corrected, this spherical power will guide the distance power of the initial contact lens. General guidance in determining the reading addition is to prescribe the lowest addition that meets the patient's visual needs at their near working distance.

Front-surface aspheric lenses, however, may occasionally be designed so that lens power is based on the total reading power or a value midway between the distance and near power. Always refer to the manufacturers' fitting advice, which is specific for that particular lens design. This is particularly important to get

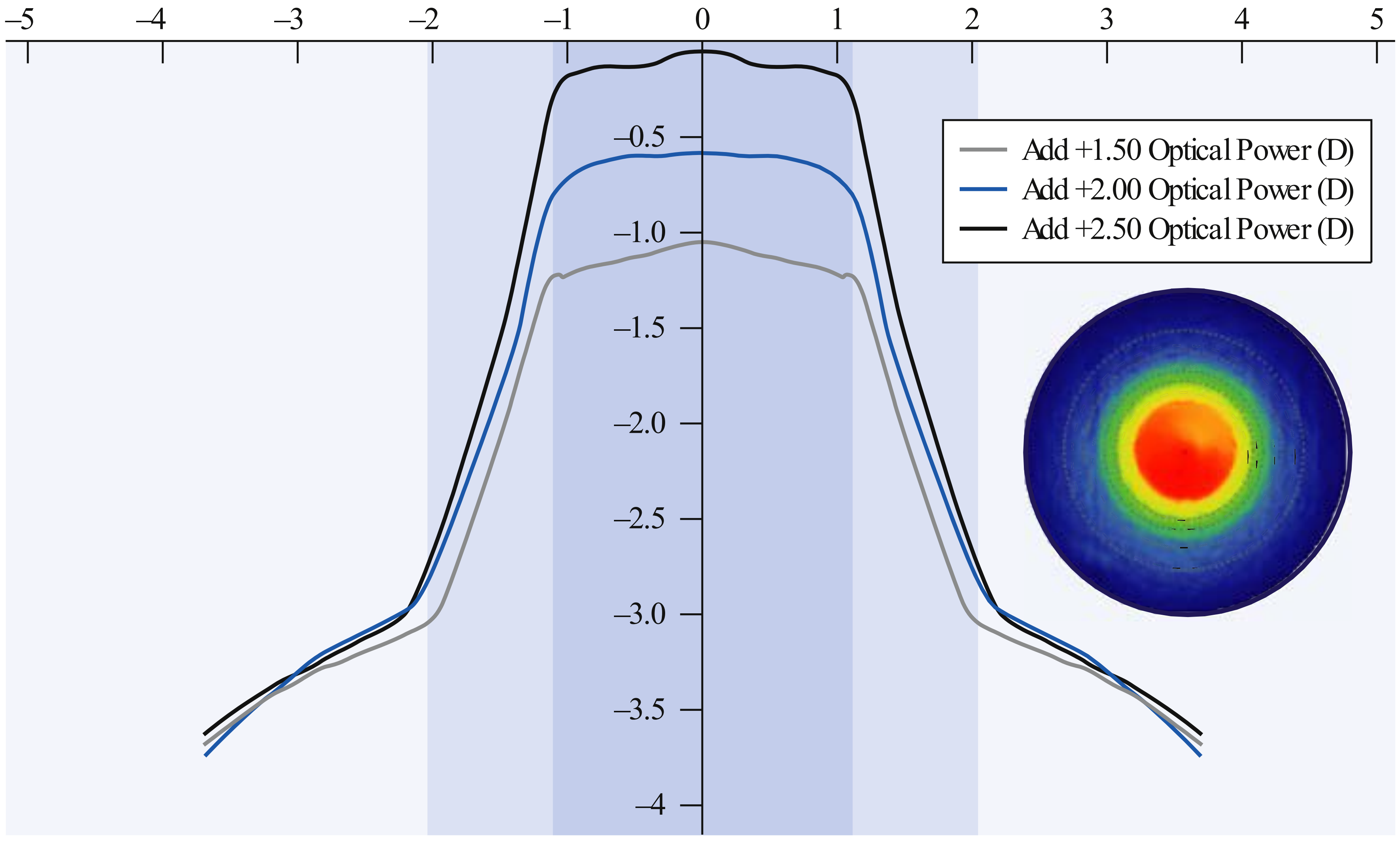

Fig. 23.14 Power profiles of the multizone concentric modified monovision design illustrating how the reduction in pupil size with age is not reflected in the design.

the best outcome for the patient with the lowest number of lens designs.

Refractive end-points are more difficult to determine when wearing a simultaneous-vision correction in each eye, and therefore the lens power selected should always be based on a current refraction. The refraction should also be carefully binocularly balanced and the best vision sphere determined as above.

The fit of a soft lens should meet the normal criteria used for single-vision soft lens fitting, as outlined in Chapter 8; however, good lens centration and minimal movement are especially critical in allowing optimal vision performance with multifocal lenses. This is even more important if fitting an aspheric lens design, as decentration may result in induced higher-order aberrations, principally coma (Efron et al., 2008). A slit lamp is of little value in determining the centration of a soft multifocal as it does not show the position of the lens centre with regard to the pupil. The technique of choice is to look at an elevation map on a corneal topographer before and after lens insertion. The ideal scenario (Fig. 23.17) shows a well-centred lens with slight nasal positioning. When decentration occurs, particularly in a temporal direction, the induced aberration results in reduced acuity (Fig. 23.18). One manufacturer uses a combination of central aspheric and peripheral spherical curves to improve lens centration. In the absence of a topographer a simple technique is to get the patient to look at a spot of light in dim conditions and draw what they see. A comet's tail extending from the light is usually a sign of a decentred lens.

Back-surface aspheric rigid lens designs are usually fitted 0.5–0.8 mm steeper than the cornea to give the desired optical effect and to obtain the required centration. Although this may seem excessively steep, the rapidly flattening aspheric back surface should result in a fluorescein pattern that shows a small central area of apical clearance surrounded by a wide area of mid-peripheral alignment (Fig. 23.19). Near performance will benefit, with this lens type, from lens translation during downward gaze.

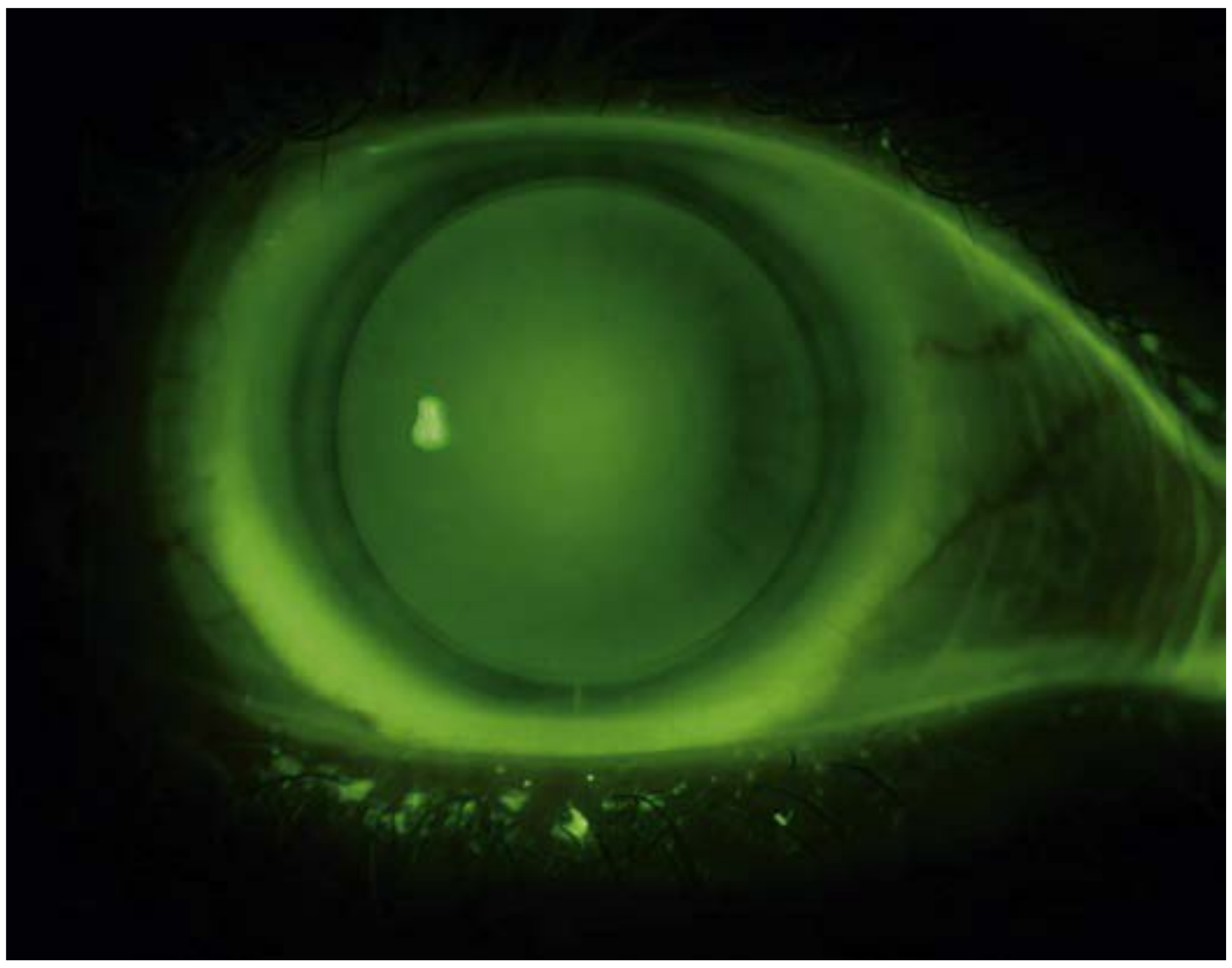

Fig. 23.15 Fluorescein patterns of a well-fitted hybrid multifocal lens. (Courtesy Sophie Taylor West.)

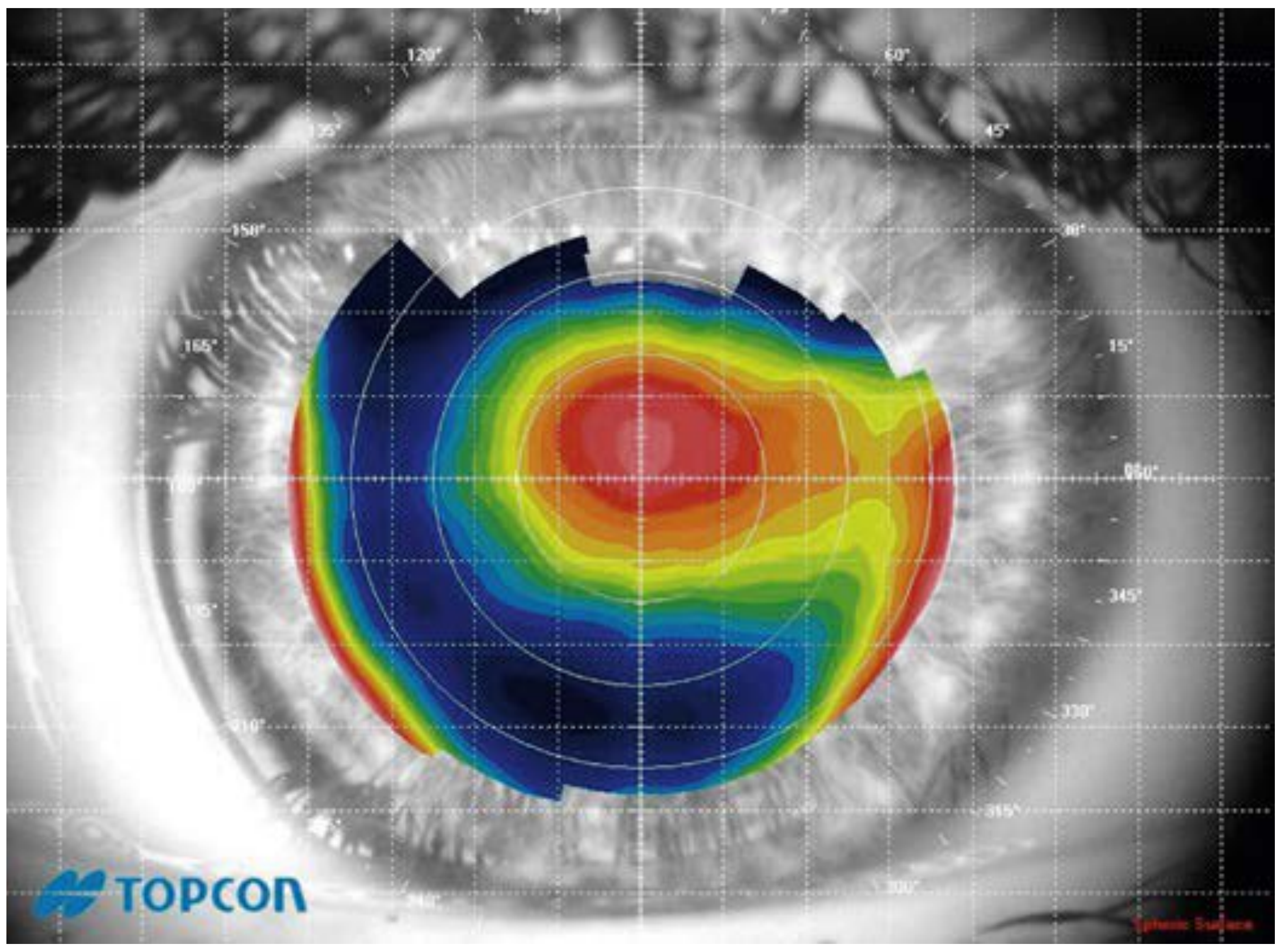

Fig. 23.17 Elevation topography map of a well-centred centre-near simultaneous-image soft multifocal lens. (Courtesy of Dr Trusit Dave.)

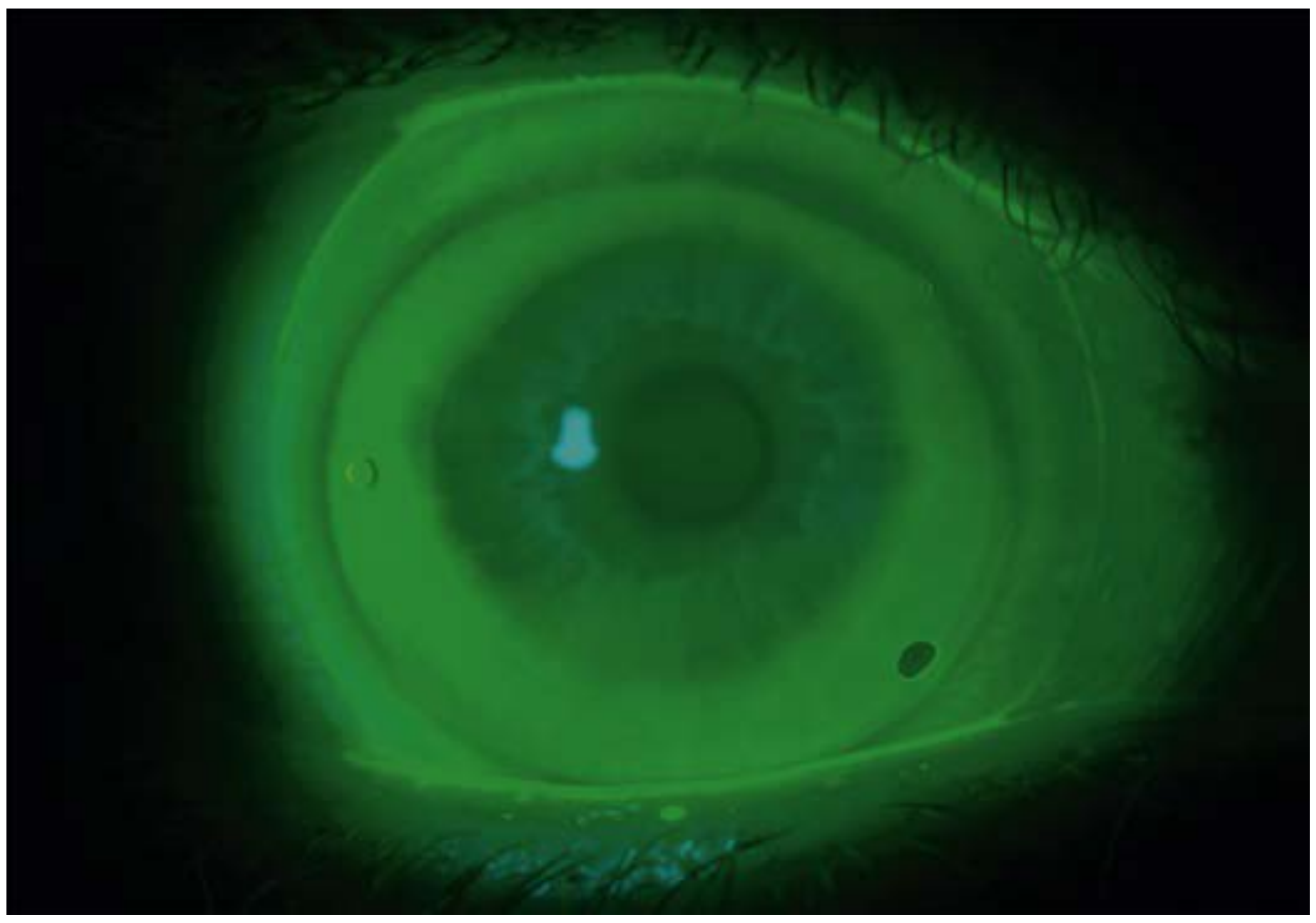

Fig. 23.16 Fluorescein patterns of a well-fitted semiscleral RGP multifocal lens. (Courtesy Sophie Taylor West.)

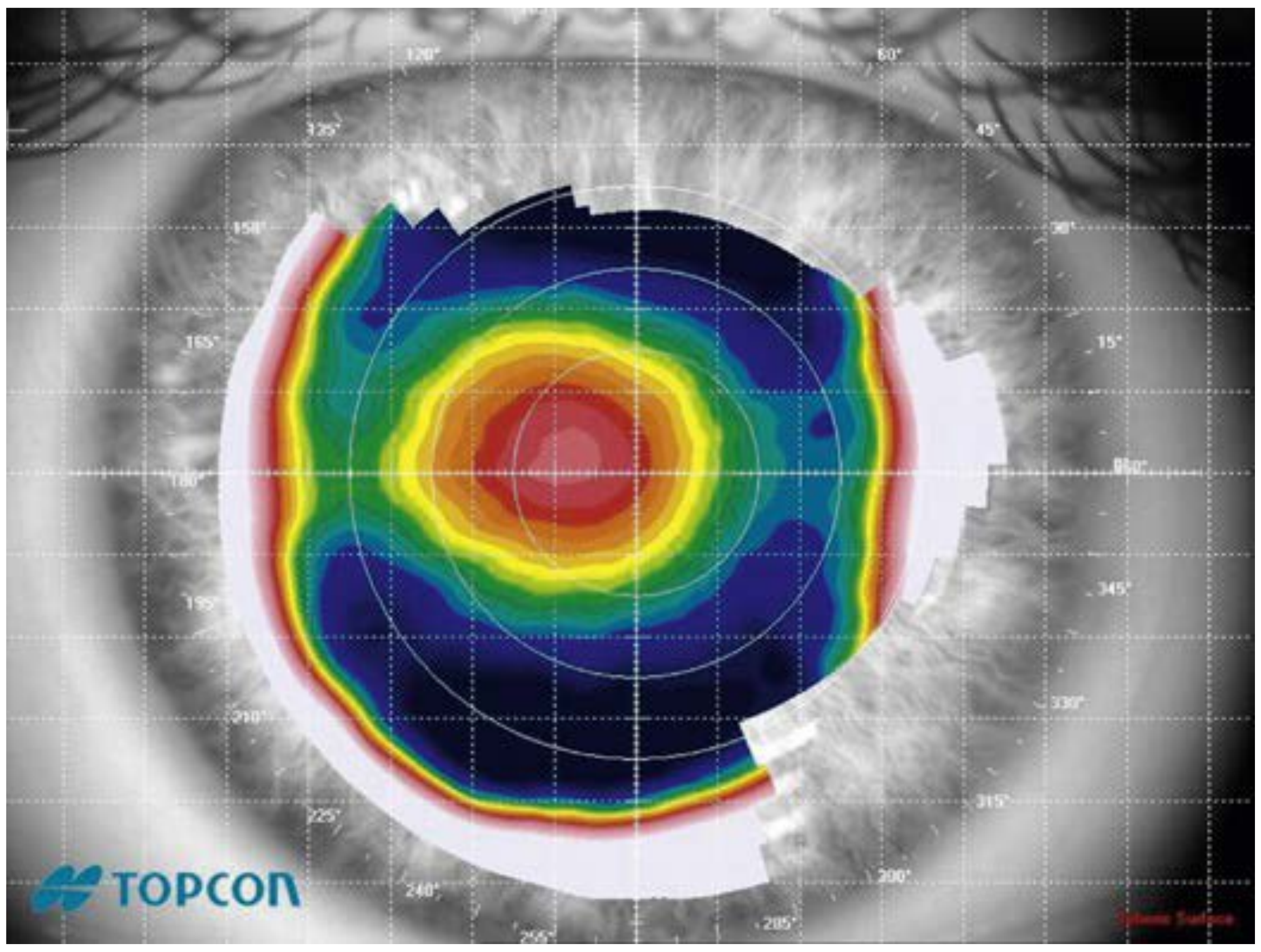

Fig. 23.18 Elevation topography map of a temporally decentred centre-near simultaneous-image soft multifocal lens. (Courtesy of Dr Trusit Dave.)

Lens Adjustments

The most common problem that the practitioner has to address with simultaneous lens fitting is poor visual performance for either distance vision or near vision, or both. The first step is to confirm lens fitting and end-point overrefraction. The most effective adjustment options may vary with the lens design being used, and once again it is critically important to follow the manufacturer's guidance. If the best vision sphere and correction for vertex distance have been made correctly, then spherical overrefraction may not be necessary and any change will be made based on the fitting guide and will involve altering the addition in one eye and / or making a small predetermined change to the spherical power of one lens.

However, some designs are sensitive to 0.25 D adjustments to the distance lens power, which can have a significant effect on distance or near visual performance. Lens power adjustments are best investigated by using ±0.25 D twirls / flippers or trial lenses during binocular vision in ambient illumination or the illumination where problems are being experienced by the wearer. The use of phoropters should be avoided during overrefraction as the resulting light reduction will increase pupil size and alter optical performance. Any distance minus-power adjustment should be made only if it has been demonstrated to make a significant impact on distance visual acuity (i.e. half to one line of Snellen visual acuity) combined with a subjective improvement. Small additional minus-power adjustments can be shown to the dominant eye first whilst investigating distance-vision improvement, or to both eyes at the same time. The former approach may lessen the risk of reducing near-vision performance whilst improving distance vision. In addition, if the parameter range allows, distance vision may be improved by reducing the reading addition by one step in the dominant or both eyes (Key et al., 1996). Adjustment options are summarized in Boxes 23.2 and 23.3. It must be stressed that these are options and that before contemplating making changes based on these tables, the manufacturers fitting guide should be followed.

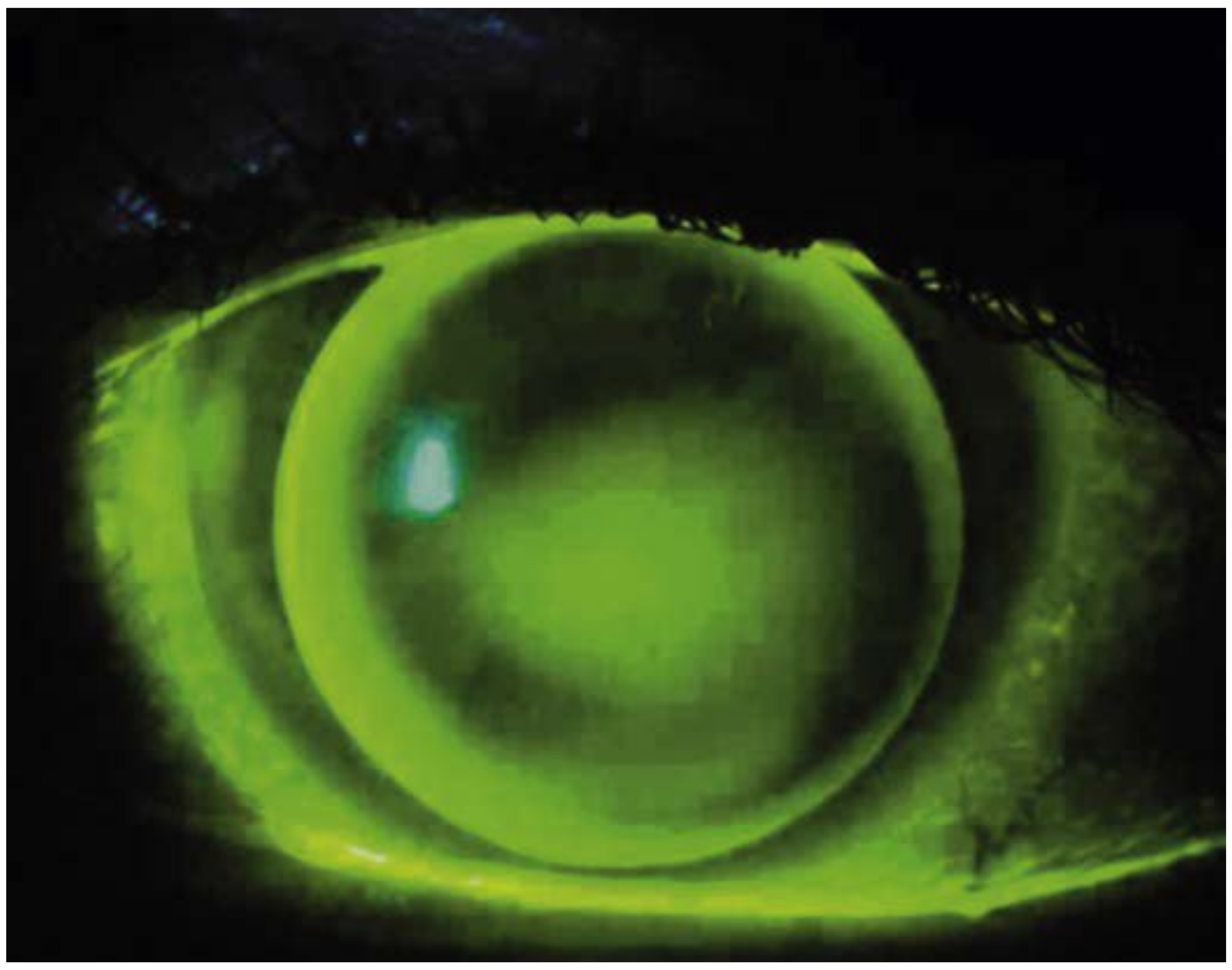

Fig. 23.19 Fluorescein pattern of high-eccentricity back-surface aspheric design showing central apical clearance and mid peripheral alignment. (Courtesy of Bruce Bridgewater.)

BOX 23.2 ADJUSTMENT OPTIONS FOR IMPROVING DISTANCE VISION DURING SIMULTANEOUS-VISION FITTING*

ADD ADDITIONAL MINUS TO DISTANCE LENS POWER

- Show more minus power in −0.25 D steps to the dominant eye first or to both eyes if necessary
- Ensure significant improvement to distance-vision performance (subjective and objective)
- Ensure near vision remains unchanged or acceptable
- Continue to add additional minus power only if further improvement is confirmed while near-vision performance is maintained

REDUCE READING ADD POWER

- If parameter range allows, reduce reading add power in one or both eyes

ALTER BACK-SURFACE FITTING RELATIONSHIP

- Some rigid lens designs require alternative fitting to achieve a change in power gradient over the pupil area and the necessary distance vision improvement

EXPLORE MODIFIED MONOVISION

- Push extra minus in dominant eye and extra plus power in non-dominant eye
- Decrease reading add by one step in the dominant eye
- Try centre-near design in one eye and centre-distance in the other

EXPLORE ENHANCED MONOVISION

- Trial single-vision distance lens in dominant eye and near-bias bifocal in the other

*NB always follow manufacturers' fitting guide initially if provided.

BOX 23.3 ADJUSTMENT OPTIONS FOR IMPROVING NEAR VISION DURING SIMULTANEOUS-VISION FITTING*

ADD ADDITIONAL PLUS TO DISTANCE LENS POWER

- Show more plus power in +0.25 D steps to the non-dominant eye first or both eyes if necessary
- Ensure significant improvement to near-vision performance (subjective and objective)
- Ensure distance vision remains unchanged or acceptable
- Adding extra lens power to non-dominant eye alone may reduce the risk of reducing distance vision performance while improving near vision

ALTER BACK-SURFACE FITTING RELATIONSHIP

- Some rigid lens designs require alternative fitting to achieve the change in power gradient over the pupil area and the necessary near-vision improvement

EXPLORE MODIFIED MONOVISION

- Push extra minus in dominant eye and extra plus power in non-dominant eye
- Increase reading add by one step in the non-dominant eye
- Try centre-near design in one eye and centre-distance in the other

EXPLORE ENHANCED MONOVISION

- Trial single-vision near lens in dominant eye and distance-bias bifocal in the other

*NB always follow manufacturers' fitting guide initially if provided.

TABLE 23.2 Causes of Poor Vision and Discomfort with Simultaneous Vision Design and Solutions

Symptom	Possible Cause	Solution
Poor vision	Poor material wettability/tear film quality	Switch to better wetting material (e.g. enhanced hydrogel daily disposable) Address any related pathology (e.g. MGD) Shorten replacement interval (e.g. go to daily disposability) Utilize tear supplements
	Inaccurate initial refraction	Recheck maximum plus spectacle BVS that does not reduce visual acuity Ensure back vertex distance compensation applied correctly Recheck spectacle reading addition is correct for working distance
	Decentered lens	If soft, either alter base curve or choose a different design of lens. If rigid, increase diameter and/or increase areas of alignment. Consider altering lid/lens attachment to raise or lower the lens
	Uncorrected astigmatism	Consider rigid or hybrid options, monovision with toric soft lenses or toric multifocal soft lens
	Exacting visual requirements	Consider 'top up' spectacles for specific activities or combine multifocal spectacles for these activities and multifocal contact lenses for other activities Consider alternating-vision contact lenses
	Unrealistic expectations	Consider same options as for exacting visual requirements but be prepared for patient not to accept any of them
	Patient's spherical aberration is higher than average negating some of lenses' and so reducing depth of focus	If centration is good then increasing the add should help. If not, changing to a different design would be the best next step.
Poor comfort	Material characteristics	For soft lenses use low coefficient of friction material. Avoid high-modulus materials and ensure wettability is high. For rigid lenses consider refitting in hybrid multifocals.
	Design characteristics	Ensure lens volume is low and edge is tapered. Ensure vision is optimized as poor vision can impact on subjective comfort.

MGD = meibomian gland dysfunction; BVS = best vision sphere.

Meeting Expectations

Although modern simultaneous image soft or rigid lenses have high rates of reported clinical success, no one lens or approach will satisfy all presbyopic patients. Lens adjustments will often need to be made to improve the optical performance based patient feedback. This is obviously more readily undertaken using soft disposable lenses, where the initial adjustment can be made at the first visit if the practitioner has a comprehensive fitting bank. For rigid lenses, the manufacturer will often make a replacement lens at little or no further cost to enhance performance.

The common reasons why lenses fail to meet patient needs, even after adjustment, and the likely solutions are set out in Table 23.2.

ALTERNATING-IMAGE (TRANSLATING) DESIGNS

The vast majority of alternating designs are available as rigid lenses owing to challenges in soft lenses translating effectively. However, in recent years a number of soft alternating-vision designs have become available, but have not become widely fitted. Both soft and rigid gas-permeable designs have distance- and near-powered portions, set out in a similar way to that observed in a bifocal spectacle lens. During primary gaze the distance portion of the contact lens is positioned over the pupil. When gaze is directed downwards during reading, the near portion translates upwards to allow near-vision correction (Fig. 23.20A and B).

Segment position and lens translation are the keys to success, and the lower lid has an important role in positioning and stabilizing the lens against the globe. The position of the lower lid should be no lower than the inferior limbus, otherwise translation is less effective and often inadequate (Fig. 23.20C). Upper-lid movement also plays an important role in lens translation, as the upward movement of the lower lid is restricted to about 0.8 mm (Borish and Perrigin, 1987). It may be more challenging to fit patients with ambient pupil sizes greater than 3 mm, as the segment has to be positioned lower to avoid the pupil margin and consequently requires greater translation to achieve adequate pupil coverage of the near portion.

General Principles of Lens Design

The two distinct portions that make up an alternating lens are either fused (encapsulated) or solid segments with a range of alternative shapes available (Fig. 23.21).

Lens stability, position and translation can be controlled by introducing prism on to the lens, truncating the lens, or both. A more recent alternating soft lens design uses prism and dynamic stabilization to orient the lens correctly and is available as a toric option. Regardless of lens design, the success of alternating-vision contact lenses is made possible by adequate lower-lid tone, which facilitates upward translation of the lens during downgaze. This positions the near portion of the lens over the pupil and allows near vision. The truncated edge should be finished in such a way as to encourage comfortable effective translation and minimize the risk of the lens slipping beneath the lower lid.

Solid Design. Designs are cut from a single piece of material and the segment shape and design can vary (see Fig. 23.21). In some older designs where the optical centres of the distance and near portion do not coincide, image jump will occur with downgaze, and lenses of 3.00 D or greater frequently result in intolerable diplopia for the wearer. For this reason, it is better to avoid lenses in these powers and use a monocentric design. In these designs the optical centres of both distance and near portions of the lens are coincident, which produces a straight-top

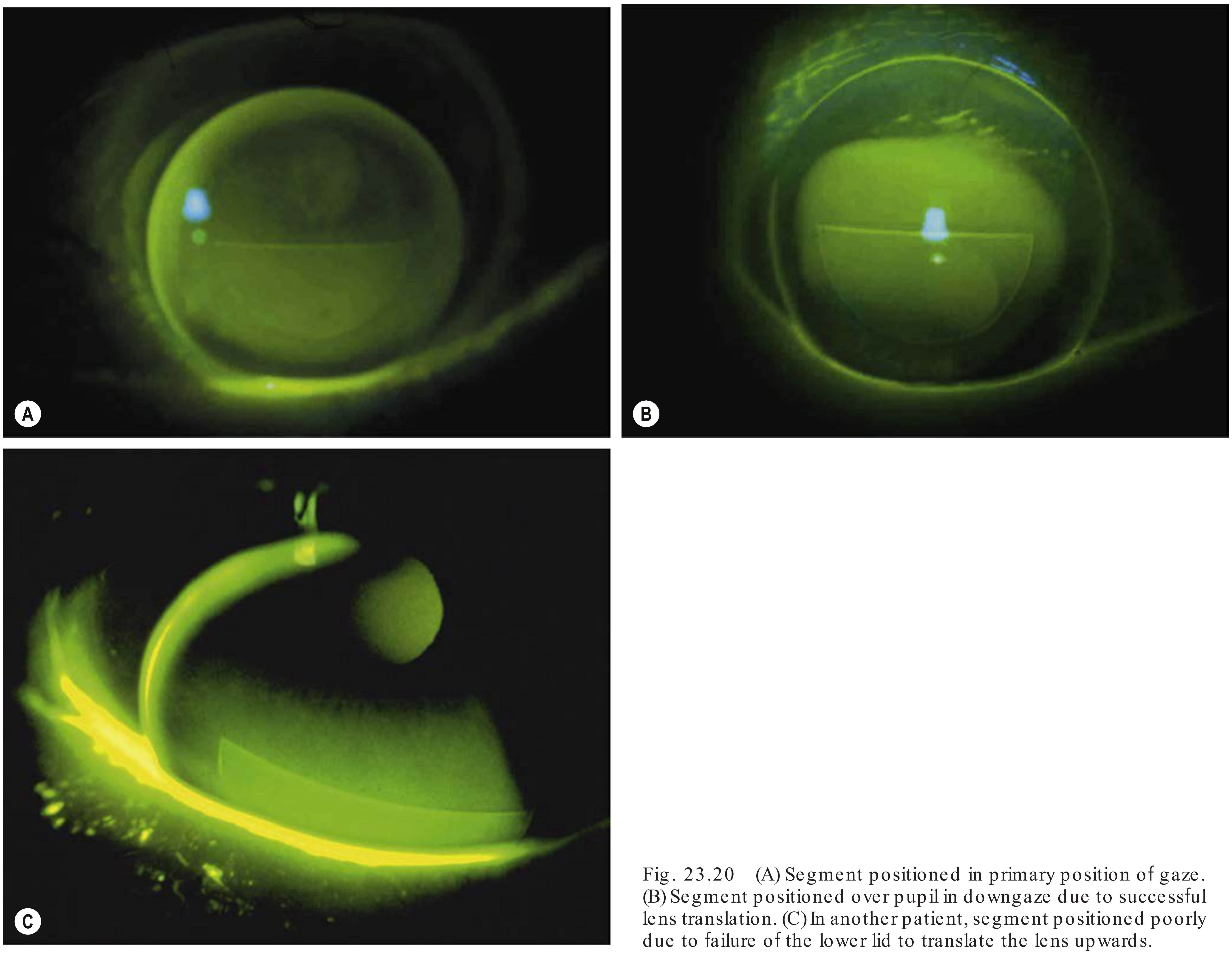

Fig. 23.20 (A) Segment positioned in primary position of gaze. (B) Segment positioned over pupil in downgaze due to successful lens translation. (C) In another patient, segment positioned poorly due to failure of the lower lid to translate the lens upwards.

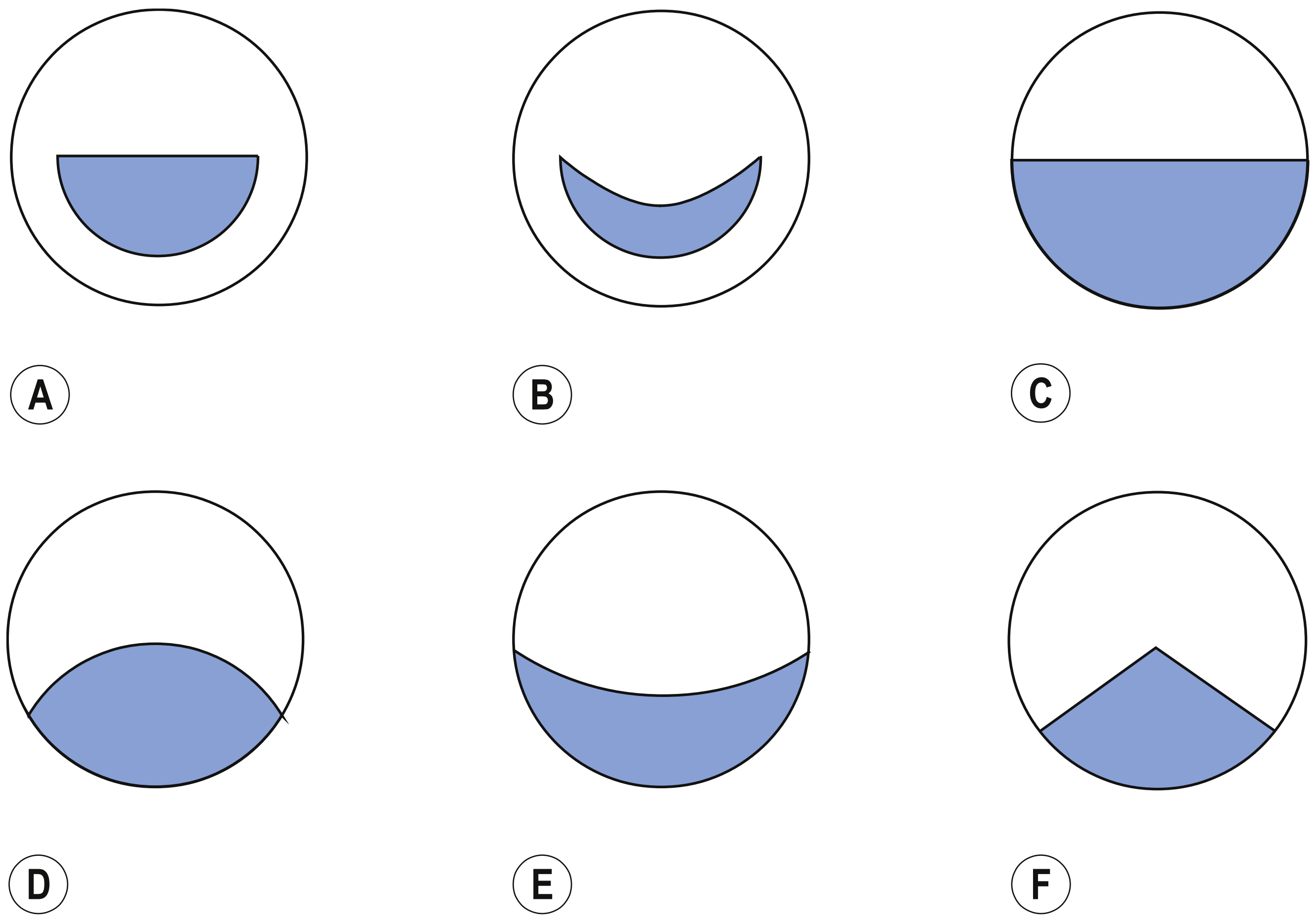

Fig. 23.21 Bifocal segment shapes. Fused: A = straight top; B = crescent. Solid one-piece: C = straight top; D = reversed crescent; E = crescent; F = triangular.

segment bifocal contact lens with the same properties as an 'executive' bifocal spectacle lens. Triangular-shaped segments are also available, which makes the design more independent of pupil diameter compared with straight-top bifocals, and often less translation is required to allow effective near correction. The design is also more forgiving if the lens rotates out of position compared with straight-top designs, and also has negligible image jump (Fig. 23.22).

Fused Design. Fused-segment rigid lenses use a fused insert of higher refractive index than the rest of the lens to generate the add power, while the front-surface curvature remains continuous. There is minimal image jump and blanks are supplied to laboratories allowing individual lens specifications to be made to order, including more complex front- and back-surface geometries. Care must be taken not to fit these lenses with the segment position too high as this increases the risk of reflections being noticed from the top of the segment (Ruston and Meyler, 1995). The fused segment is fluorescent, allowing easy observation using a Burton lamp.

Lens Fitting

Alternating rigid lenses are generally fitted on alignment or with minimal apical corneal touch. The truncation should rest on the lower lid. The lens should have a vertical diameter at least 2 mm smaller than the horizontal visible iris diameter; this encourages the required inferior centration and rapid recovery of lens

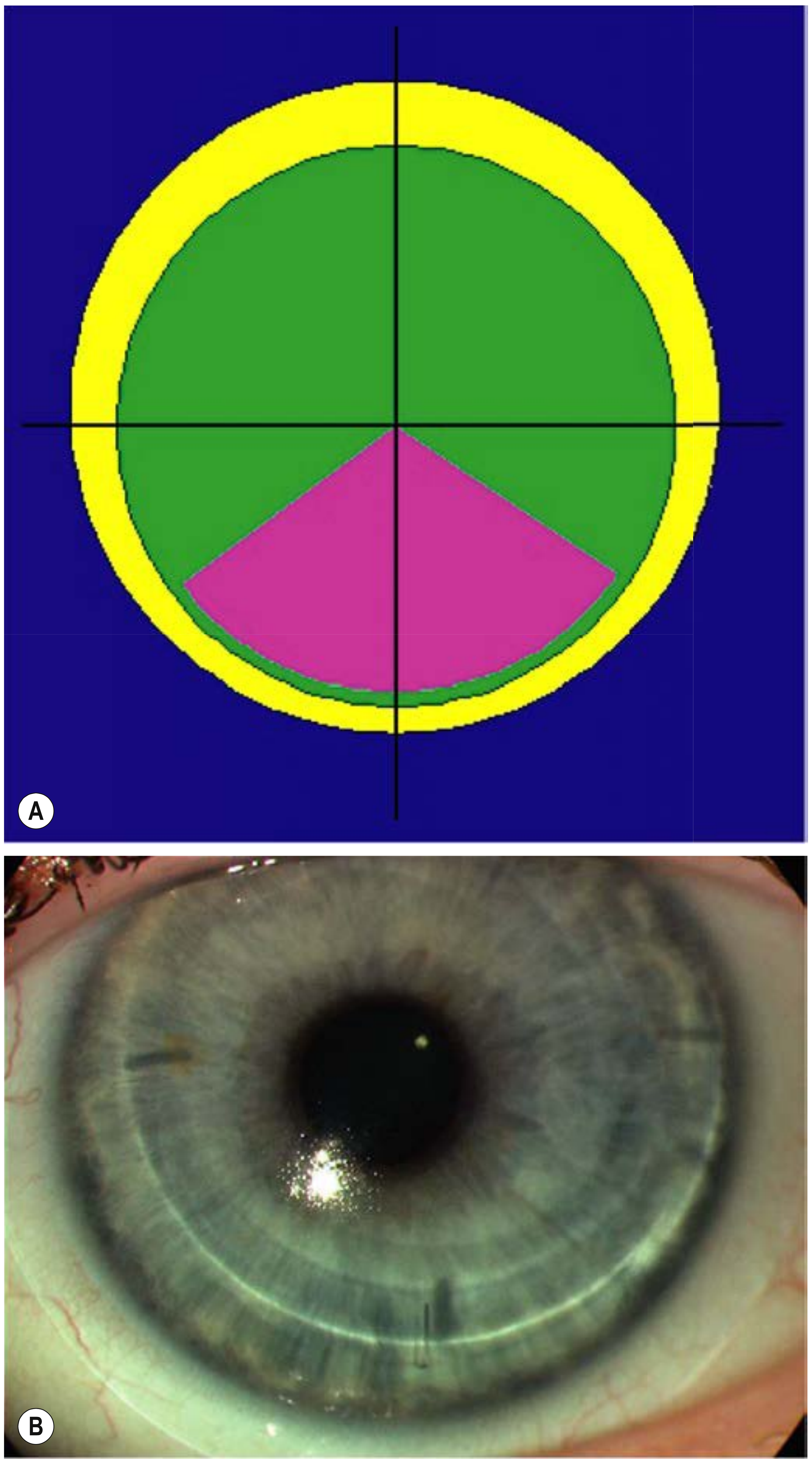

Fig. 23.22 (A) Triangle-shaped segment design. (B) Triangle-shaped segment in primary position of gaze. (Courtesy of David Ruston.)

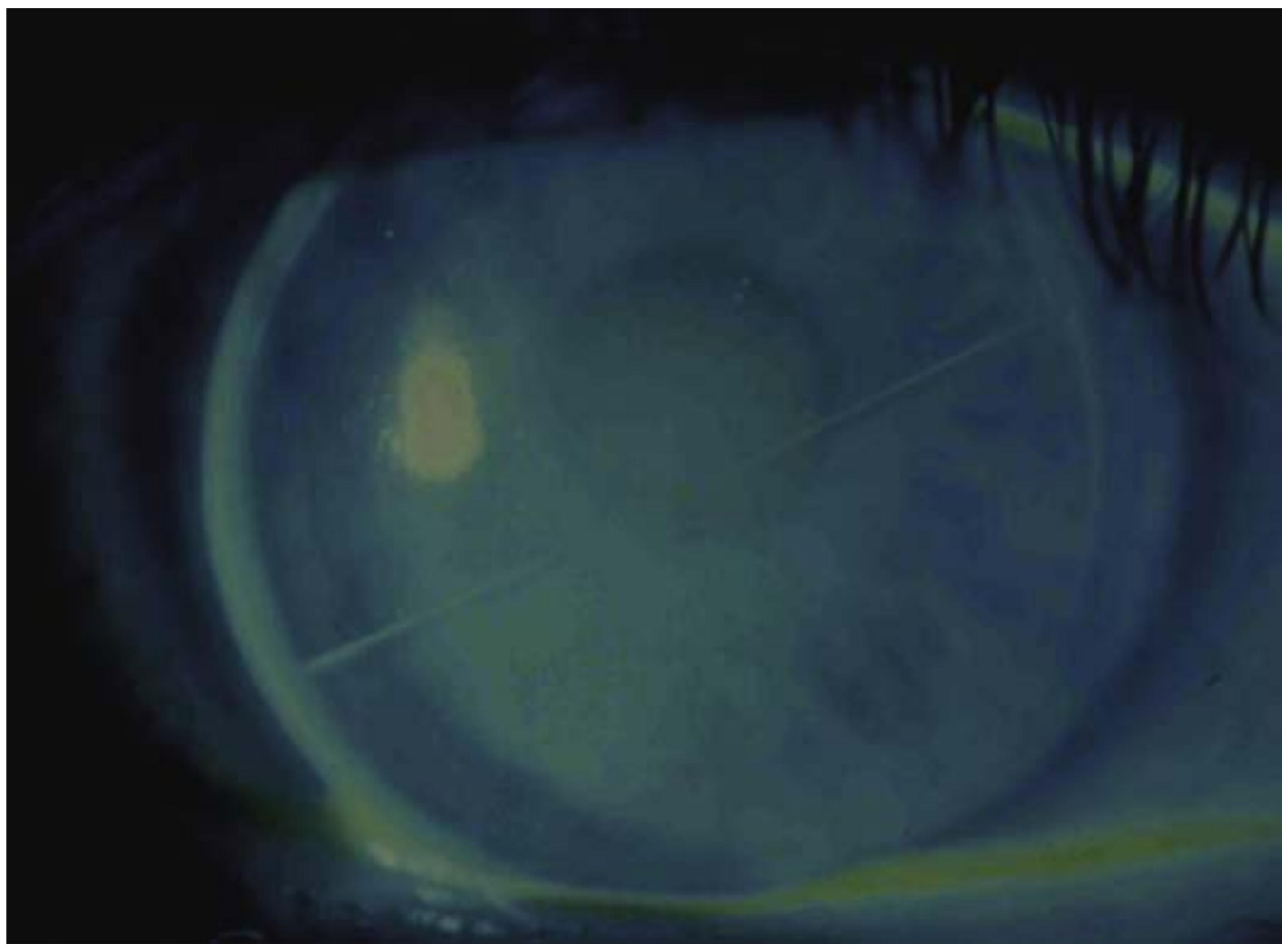

Fig. 23.23 Nasal rotation resulting from a steep-fitting translating image lens. (Courtesy of David Ruston.)

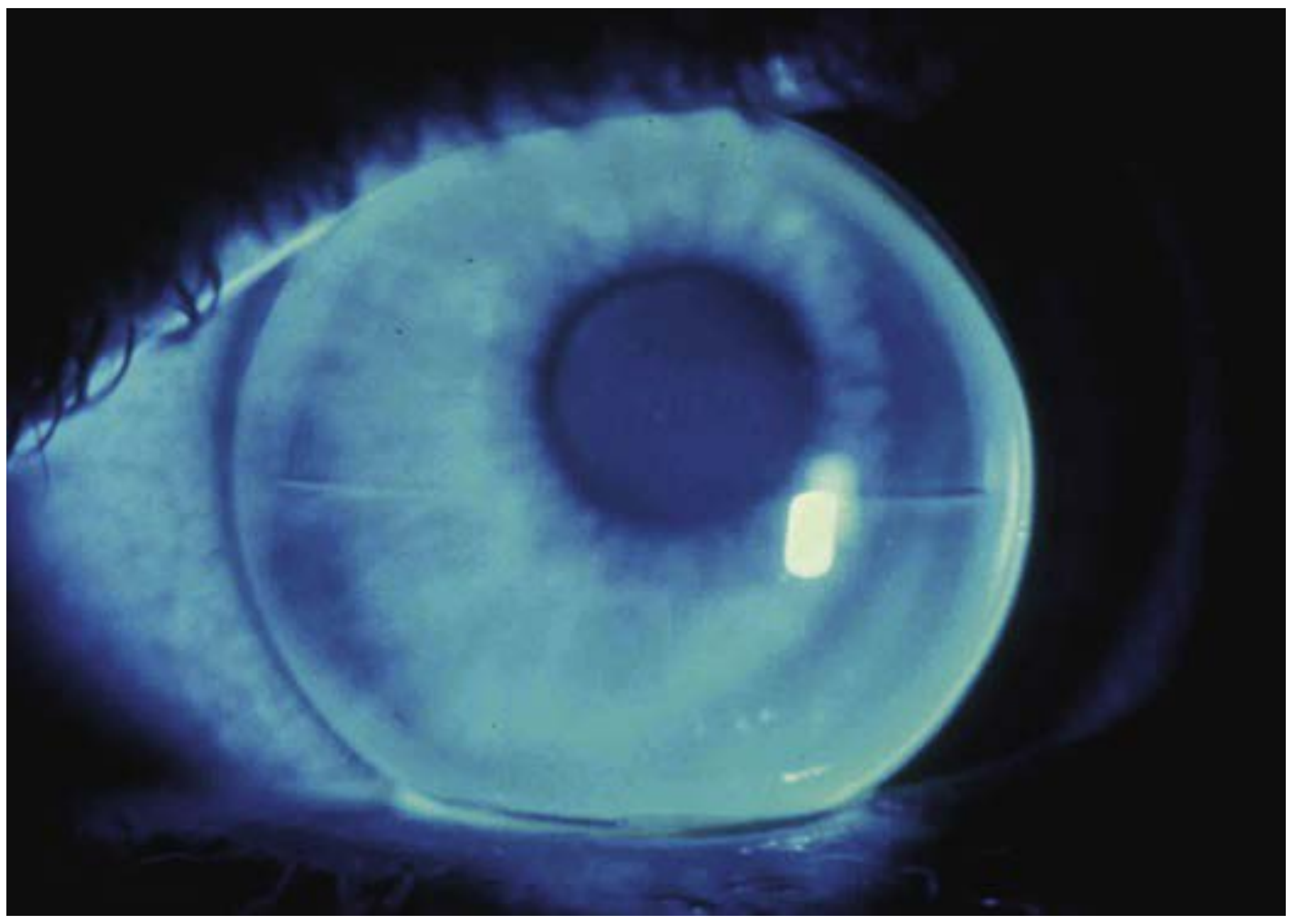

Fig. 23.24 Ideal segment line position of a straight-top solid design for distance vision.

position following blink as well as upward movement during depressed gaze. Translation over the corneal surface is more likely if there is unimpeded vertical movement, so a steep-fitting approach should be avoided. In general, a lens fitted too steeply will tend to rotate nasally (Fig. 23.23) and shows poor translation, unlike a flat lens fit, which rotates temporally and decentres.

Most alternating bifocal contact lenses are fitted so that the segment is positioned in line with the inferior pupil margin during primary gaze in ambient illumination. Alternatively, some solid designs are such that the segment should be fitted higher to occupy approximately 20% of the pupil area (Fig. 23.24).

More importantly, the near segment should occupy at least 75% of the pupil diameter during depressed gaze to allow adequate near vision. As a general rule, it is best to err on setting the segment top slightly high as this can subsequently be lowered by increasing truncation (Gasson and Morris, 1998). A near-horizontal segment line position is preferred; however, a small amount of nasal rotation is acceptable because the natural convergence of the eyes at near helps offset this rotation (Edwards, 1999).

Observing segment positions under slit-lamp illumination can be deceptive owing to the resultant pupil miosis. A better assessment can be made using an ophthalmoscope focused on the lens surface. If an optimal alignment fit shows significant rotation away from the desired position, the lens can be reordered with prism offset by the angle through which the lens mislocates to compensate for the rotation. For example, if the lens persists in rotating by 15° nasally in the right eye, ordering the prism base at 285° rather than 270° orients the lens correctly. Increasing the amount of prism can also be useful in reducing superior centration. Discomfort and adequate oxygen delivery (mainly due to lens thickness) are still challenges for soft alternating designs.

MONOVISION

Monovision is the correction of one eye with the required distance refractive power and the other eye with the required near refractive power. This approach is based upon the principle that

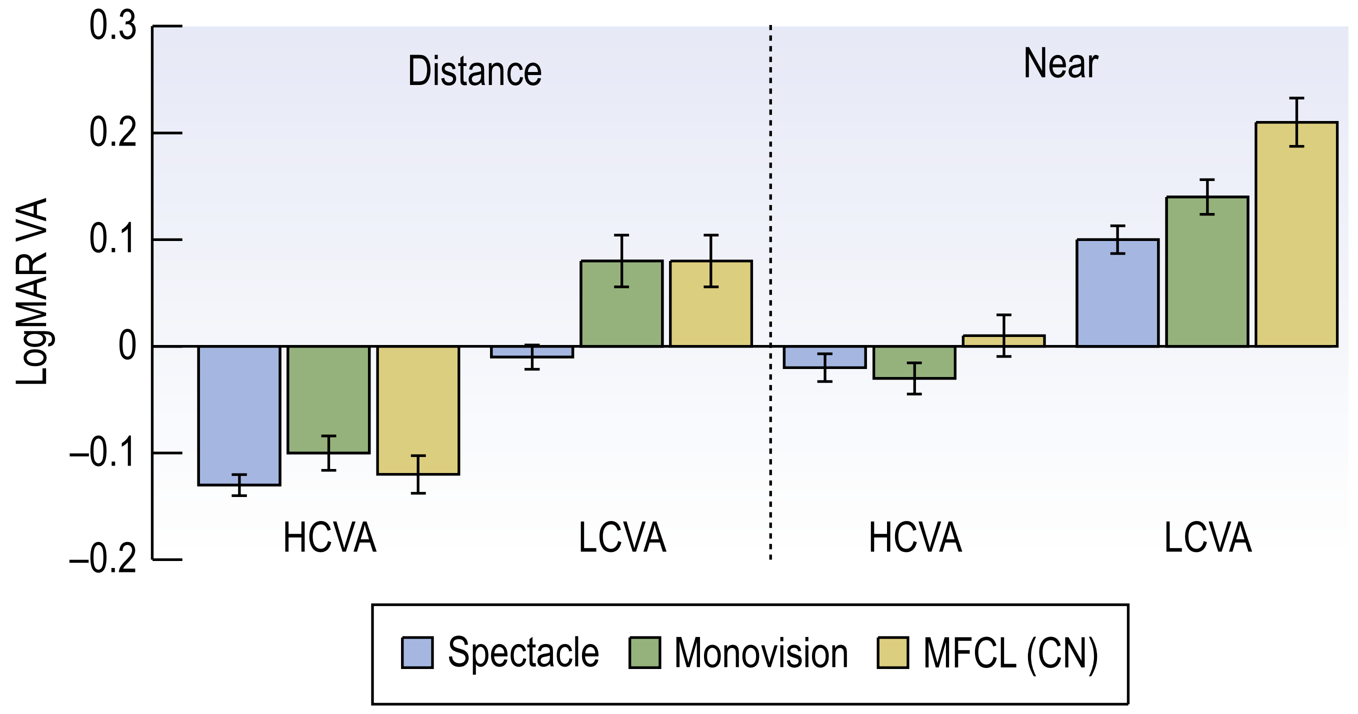

Fig. 23.25 LogMAR acuity at distance and near at two contrast levels for spectacle, monovision and simultaneous-image multifocal correction.

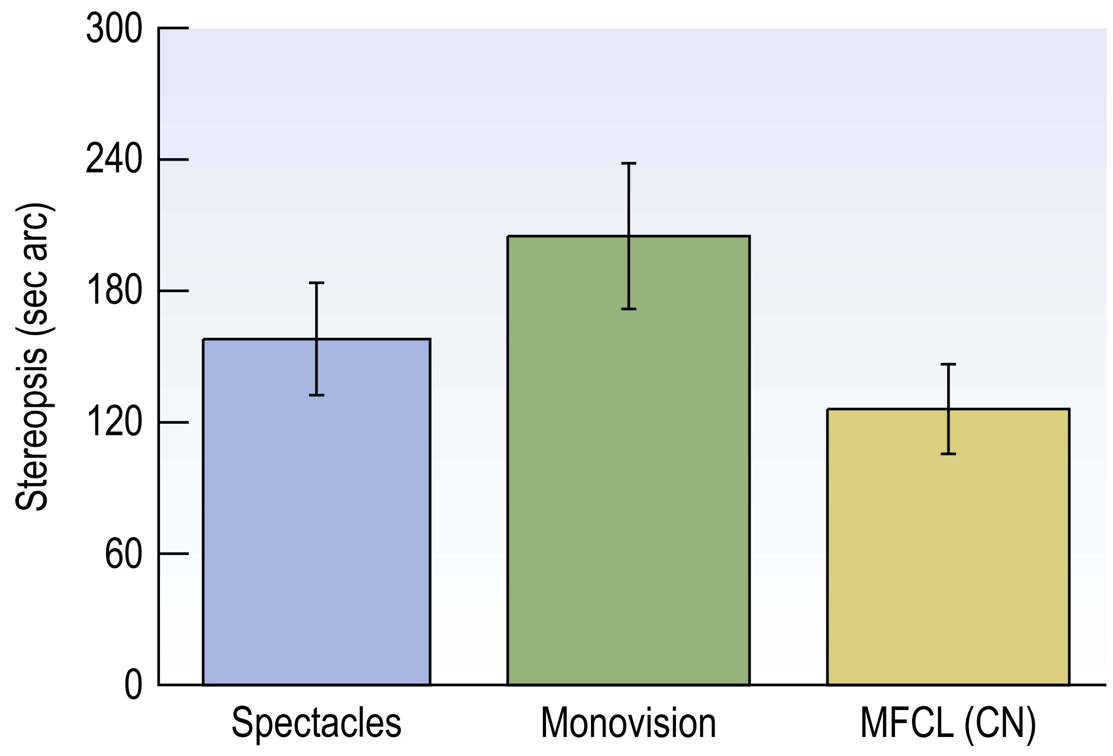

Fig. 23.26 Near stereopsis measures for spectacles, monovision and centre-near (CN) multifocal contact lens (MFCL) wearers.

the visual system can alternate central suppression between the two eyes when viewing is alternating between distance and near targets. The degree of interocular blur suppression, which varies between patients, may be linked to the final success of monovision. Essentially all forms of soft and rigid contact lenses can be used for monovision corrections, whether spherical or toric. The more recent availability of new hydrogel materials with embedded wetting agents and silicone hydrogel materials, some of which can reduce lens-related dryness symptoms in this age group, are also helpful when fitting monovision.

With monovision correction, there is only a slight reduction in performance in distance acuity tests compared with spectacle correction, and no significant difference in acuity results at near vision (Back et al., 1992). When comparing spectacle, monovision and simultaneous-image centre-near lenses, results for high-contrast and low-contrast visual acuity at distance were comparable (Richdale et al., 2006), with some losses for both monovision and simultaneous vision in low contrast at near (Fig. 23.25). Distance and near stereopsis is compromised with monovision (Richdale et al., 2006) (Fig. 23.26), but the degree of reduction is patient specific and may or may not result in failure with this method of fitting.

Contrast loss and difficulty in suppressing bright images against dark backgrounds (e.g. car headlights) while wearing monovision lenses may also contribute to poor tolerance (Schor et al., 1987). Glare when driving at night is the most common complaint and this should be discussed with the potential monovision wearer during the initial fitting assessment. Despite such compromises, monovision has historically had high patient acceptance in early and moderate presbyopia with success rates varying from 67 to 86% (Koetting and Castellano, 1984; Back et al., 1989; Collins et al., 1994). Monovision causes little compromise in near visual acuity performance in all illumination conditions; thus, this type of fitting option could be considered for presbyopic patients with strong near-vision demands when multifocal options have failed. However, when critical or sustained tasks requiring good binocularity predominate, it is advisable to avoid monovision or to consider supplementary correction.

Although visual acuity measures may compare favourably with spectacle correction, this form of correction has several limitations. Whereas binocular high-contrast visual acuity is similar to that in multifocals, contrast sensitivity function is reduced binocularly (Rajagopalan et al., 2006; Richdale et al., 2006). When wearers have experienced both modes of correction, most prefer multifocals to monovision (76 versus 24%) (Richdale et al., 2006)

It is also important to remember that success with monovision and clarity of intermediate vision decline as the required addition and interocular disparity increases (Evans 2007). It is for this reason that many practitioners now prefer to introduce multifocal contact lenses to patients at the onset of presbyopia, with the belief that they can remain in this mode of correction longer than with monovision. The current preference for multifocal contact lenses over monovision is evident from a survey of multifocal versus monovision prescribing in 34 countries in 2015 (Fig. 23.27) (Morgan et al., 2016). Although the extent of prescribing for presbyopia varies between the nations surveys, it is clear than multifocal lenses are the preferred choice. It may now be considered that monovision should be employed only when multifocal contact lenses are not available or have not adequately satisfied the patient's visual needs.

General Principles of Monovision Fitting

No single predictive test exists to identify successful monovision patients, so systematic trial and error is the best approach. However, the initial impression of the patient can be an important indicator of likely success. The more usual fitting approach is to fit the dominant eye with the distance-vision-correcting lens and the non-dominant eye with the near-vision-correcting lens (Jain et al., 1996; Maldonado-Codina et al., 1997). It is important to correct any astigmatism equal to or greater than 0.75 D in either or both eyes; uncorrected astigmatism can result in reduced visual performance, asthenopic symptoms and poor tolerance. Binocular visual acuity similar to that achieved with the spectacle correction – with no significant reduction in stereopsis or contrast sensitivity – is usually a good sign of likely success.

Some patients require spectacles for deficiencies with monovision to wear 'over' their monovision contact lens correction. For example, there may be a requirement for extra minus correction over the near-correcting lens/eye and plano over their distance-correcting lens to give full binocular vision and optimal distance acuity for night driving, especially when higher reading additions are required. The degree of interocular blur suppression, which varies between individuals, may be linked to the final success of monovision.

Partial Monovision

In general, the acceptance and therefore success of monovision falls as the reading add increases (Schor et al., 1987; Erikson, 1988, Evans 2007). With reading adds over +2.50 D at low levels of illumination or with near-threshold stimuli, visual performance of monovision wearers is reduced (Johannsdottir and Stelmach, 2001). As the effective add increases, binocular stereoacuity has also been shown to decrease (Heath et al., 1986). As the indicated add exceeds +2.00 D, tolerance can often be improved if a reduced reading addition is given. The patient may need supplementary glasses for small print, a different pair of supplementary glasses for driving or a secondary distance-correcting contact lens. This form of monovision is ideal for social users whose near-vision demands will be lower than that of full-time wearers. Partial monovision may also be a useful strategy for patients who have greater intermediate-vision needs.

Enhanced Monovision

Enhanced monovision – which is considered by some to be a modified monovision fitting approach – involves fitting one eye with a multifocal lens and the other with a single-vision lens. A variety of options exist. The most frequent approach involves fitting the dominant eye with a single-vision distance lens (spherical or toric) and the non-dominant eye with a multifocal lens. This improves binocular summation provided that the induced optical disparity remains low and offers some level of stereoacuity to the monovision wearer who is experiencing increasing blur with a higher reading add. Alternatively, the same approach can be used when fitting patients who require sharper distance vision than bilateral simultaneous image can offer. The multifocal lens in the non-dominant eye may need more bias for near vision. This modification can be achieved effectively by increasing the distance power of the multifocal lens by +0.50 D to +0.75 D.

Other enhanced monovision options include:

- a single-vision near lens in the dominant eye to improve near vision and a distance-bias multifocal lens in the non-dominant eye
- a single-vision lens with slightly excess plus power in the dominant eye and an intermediate-bias multifocal lens in the non-dominant eye

A summary of the different problem-solving approaches for monovision fitting is shown in Fig. 23.28.

Monovision remains an effective approach for some presbyopic patients and can offer less objective visual compromise than simultaneous image lenses in high- and low-contrast visual environments. However, a study by Dutoit et al. (2000) has shown that adapted monovision wearers rated many aspects of subjective vision performance – such as distance vision in good and poor lighting, driving at night and depth perception – to be superior with simultaneous image multifocal contact lenses. Near vision in poor lighting was rated higher during monovision wear. Subjects with no previous experience of presbyopic contact lens correction preferred monovision compared with multifocal correction (58% versus 42% if excluding spectacle lens preference).

Modified Monovision

Modified monovision involves adjusting the refractive power of the lens or selecting alternative lens designs for each eye to improve distance vision deliberately in one eye, at the expense of near performance in that eye, while improving near vision in the other. This can be achieved by increasing minus power / decreasing plus power on the dominant eye to enhance distance vision while decreasing minus power / increasing plus power in the non-dominant eye. A similar bias can be obtained

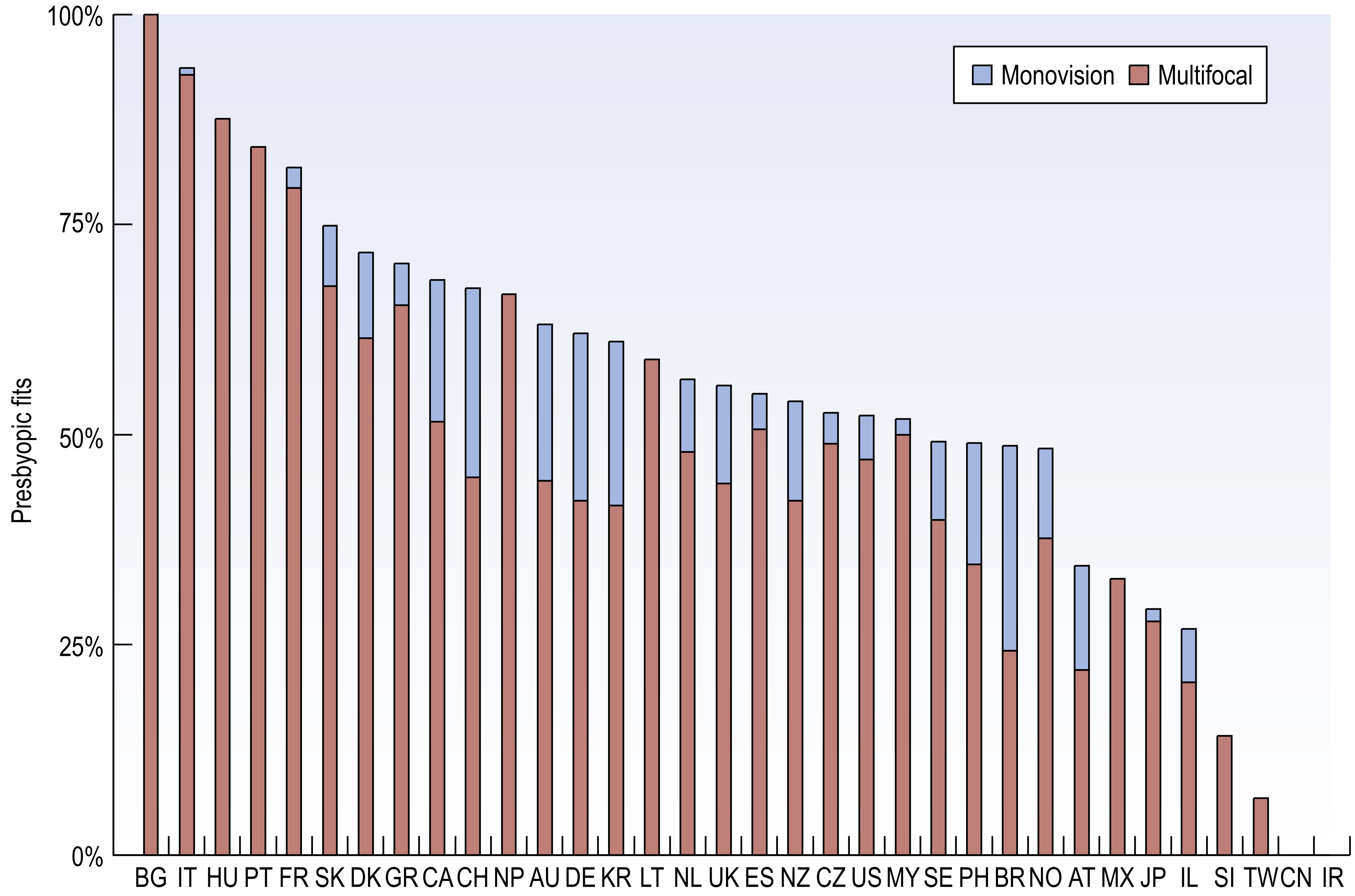

Fig. 23.27 Multifocal and monovision contact lens fits as a proportion of all soft lens fits to presbyopes (those over 45 years of age) in 34 nations in 2015. Country codes: AT = Austria; AU = Australia; BG = Bulgaria; BR = Brazil; CA = Canada; CH = Switzerland; CN = China; CZ = Czech Republic; DE = Germany; DK = Denmark; ES = Spain; FR = France; GR = Greece; HU = Hungary; IL = Israel; IR = Iran; IT = Italy; JP = Japan; KR = Korea; LT = Lithuania; MX = Mexico; MY = Malaysia; NL = Netherlands; NO = Norway; NP = Nepal; NZ = New Zealand; PH = Philippines; PT = Portugal; SE = Sweden; SI = Slovenia; SK = Slovakia; TW = Taiwan; UK = United Kingdom; US = United States.

by using different add powers in each – the lower-add power being fitted to the dominant eye to improve distance vision. Similarly, one eye may be fitted with a centre-distance simultaneous design and the other with a centre-near design lens. More recently lens designs are available that use this modified-monovision approach automatically when fitting presbyopic patients. As noted previously, the amount of optical disparity needs to be low to maintain binocular summation.

Conclusion

The key to meeting the visual needs of a presbyopic patient is the development of an awareness of the different fitting approaches and lens designs, and the associated advantages and disadvantages of each (Table 23.3).

It is equally important to gain an appreciation of the personality, occupation and previous lens-wearing history (if any) of the patient. Presbyopia correction is often perceived by practitioners as being complicated to fit, with limited success rates; however, there are now more lens options than ever to offer our presbyopic patients, resulting in higher fitting success rates than previously. No correction option for presbyopia (including spectacles) is without some compromise and the lack of a ‘perfect’ contact lens option should not discourage practitioners from fitting this ever-increasing patient base. New simultaneous designs with improved optical performance and fitting approach are now relatively easy to prescribe, supported further by the availability of single-use diagnostic lenses that allow effective trials to help eliminate failures prior to dispensing. Daily disposable multifocal lenses are also available for patients, offering even greater levels of convenience whether worn every day or part-time. There are multifocal lens designs available in enhanced hydrogel, silicone hydrogel and high-permeability rigid lens materials, which may enable continuous wear of the lenses (Lakkis et al., 2006).

If the initial lens powers selected fail to provide adequate visual performance, alternative fitting approaches, such as

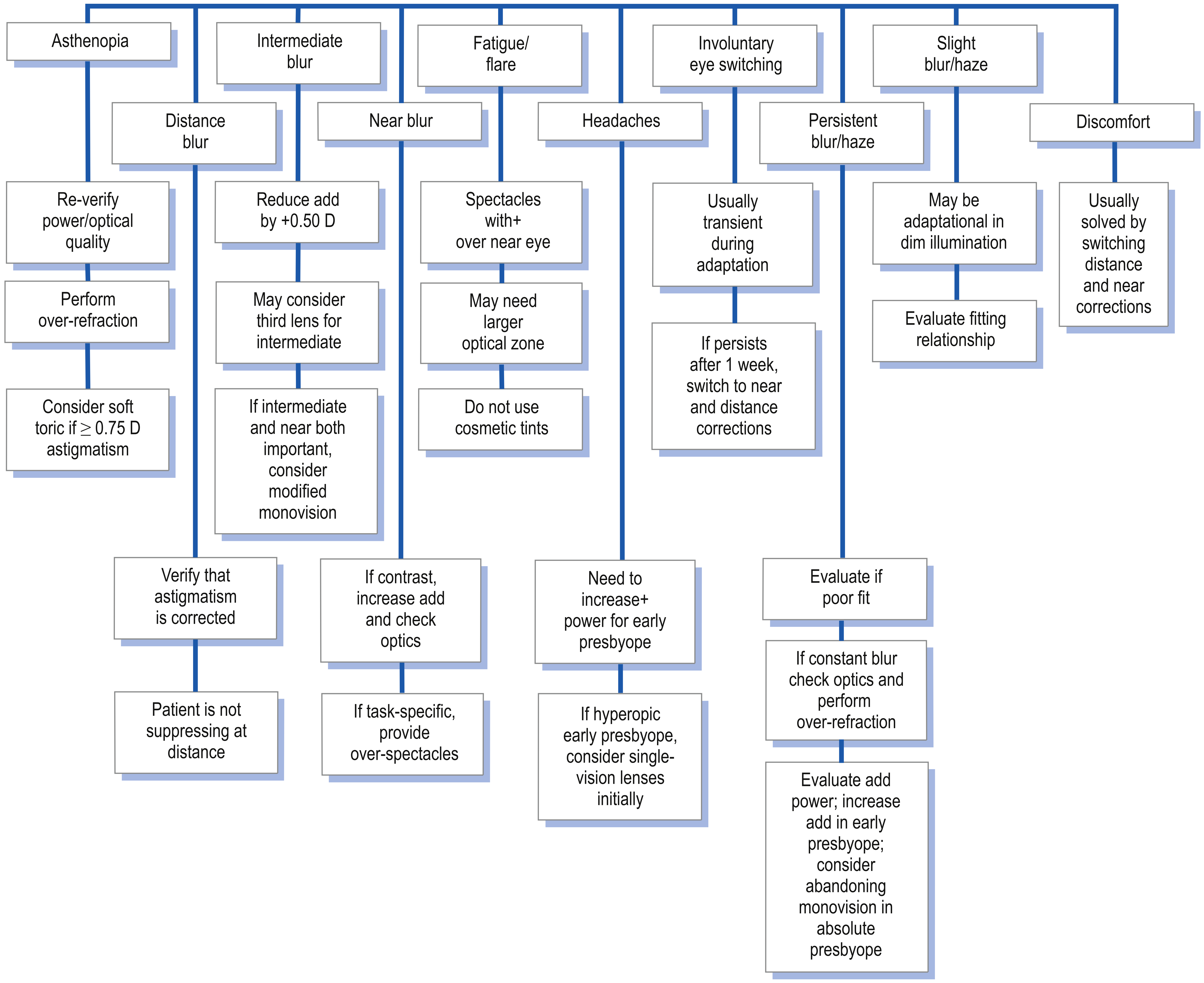
Asthenopia
Intermediate blur
Fatigue/ flare
Involuntary eye switching
Slight blur/haze
Distance blur
Near blur
Headaches
Persistent blur/haze
Discomfort
Re-verify power/optical quality
Perform over-refraction
Consider soft toric if ≥ 0.75 D astigmatism
Reduce add by +0.50 D
May consider third lens for intermediate
If intermediate and near both important, consider modified monovision
Spectacles with+ over near eye
May need larger optical zone
Do not use cosmetic tints
Usually transient during adaptation
If persists after 1 week, switch to near and distance corrections
May be adaptational in dim illumination
Evaluate fitting relationship
Usually solved by switching distance and near corrections
Verify that astigmatism is corrected
Patient is not suppressing at distance
If contrast, increase add and check optics
If task-specific, provide over-spectacles
Need to increase+ power for early presbyope
If hyperopic early presbyope, consider single-vision lenses initially
Evaluate if poor fit
If constant blur check optics and perform over-refraction
Evaluate add power; increase add in early presbyope; consider abandoning monovision in absolute presbyope

Fig. 23.28 Problem-solving approaches for monovision fitting. (Adapted from Bennett, E. S., Jurkus, J. M. & Schwartz, C. A. (2000). Bifocal contact lenses. In E. S. Bennett & V. A. Henry (eds) Clinical Manual of Contact Lenses (2nd ed., pp. 410–449). Philadelphia, PA: J. B. Lippincott Co.)

TABLE 23.3 Advantages and Disadvantages of Lens Fitting Options for Presbyopia Correction

Advantages	Disadvantages
SIMULTANEOUS IMAGE	
Available in both rigid and soft designs	Some visual adaptation required by patient
Vision in all directions of gaze	Some contrast loss always occurs, especially in low luminance
Latest designs have high fitting success rates	More difficult to establish refractive end-point during overrefraction
Stereoscopic vision maintained	Optical performance can depend on pupil size (varies with design)
No rotational stability required	Lens centration more critical
Usually more comfortable than alternating designs	
Available as single-use soft disposable trial and prescription lenses	
Easier to fit than alternating designs	
ALTERNATING IMAGE	
Distance and near acuity can be comparable with spectacle correction	Fitting more complex
Minimal reduction in stereopsis	Performance gaze dependent
Minimal reduction in contrast	Intermediate correction not always an option
	Lid position and tightness critical to success
	Comfort can be lower than simultaneous vision designs
MONOVISION	
Simple fitting method	Significant reduction in stereopsis (especially at near); however, patient dependent
Binocular high-contrast visual acuity similar to spectacles	Unsuitable for monocular patients or those with significant amblyopia (6/12 or worse)
Large range of lens designs/materials to choose from	Loss of contrast sensitivity
Less expensive than multifocal options	Reduced intermediate correction as reading add increases
No additional fitting sets required	Success rate falls as reading add increases
Patients quickly accept or reject technique	Headlight glare can be difficult to tolerate
Can easily correct astigmatism	Reduced binocular summation

TABLE 23.4 Clinical Pearls for Presbyopia Fitting

- Set realistic expectations upfront. Success is what is right for the patient and remember the 20/happy rule
- Decide your clinical strategy with each patient and avoid trying different designs based on the same optical principle. Consider different approaches, including modified monovision and enhanced monovision
- Study and follow the manufacturer's fitting advice for any one particular design of lens, as they all differ slightly in design characteristics and optimal fitting
- Always assess vision performance with both eyes open using real-world targets, such as the patient's mobile phone. Let the patient trial lens performance at home and work, and have the patient return a week later for follow-up assessment
- Avoid phoropters for overrefraction. Trial frame or flippers are best and look for an improvement in overall vision. Use the Snellen letter chart only to record visual acuity for legal purposes and as a benchmark for future lens changes
- Always look for the optimal balance between near and distance vision that meets the patient's visual needs

(Adapted from Christie and Beertren, 2007)

enhanced and modified monovision, can be explored. Key fitting tips are summarized in Table 23.4.

Alternating designs can be added to the lens choice to offer patients bifocal correction if more exacting visual performance is required. In addition, monovision remains an alternative option for some presbyopic patients. No one lens design will work for all patients, therefore it is recommended that practitioners select and use two to three alternative lens designs so that a sound clinical approach can be developed and used with confidence. There is no doubt that, with recent improvements in optical design, material choice and greater availability of daily disposable products, the number of patients being fitted with contact lenses for presbyopia will continue to increase, allowing existing wearers to enjoy the benefits of lens wear and new wearers to be fitted at the onset of presbyopia.

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Access the complete references list online at http://www.expertconsult.com.

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24

Extended Wear

NOEL A BRENNAN | M-L CHANTAL COLES

Introduction

Practitioners and researchers have long sought to develop a lens that can be worn on an extended basis. The term 'extended wear' (EW) has generally been applied to describe wear of contact lenses for periods in excess of 24 hours between removal, including sleep with the lenses on eye and regular, planned removal of the lenses. The term 'continuous wear' was originally used to describe prolonged wear of unspecified duration, but was discarded during the early 1980s because prolonged wear was considered to be an unachievable goal. In the late 1990s, 'continuous wear' was reintroduced as a term to describe intended lens wear of up to 30 days between removals. To a certain extent, the terms are used interchangeably, but for the purposes of this chapter, the term 'extended wear' will be used.

The demand for more convenient forms of optical correction has increased over the years. Numerous marketing surveys have revealed the desire of the majority of the contact-lens-wearing population for EW. Various factors influence this desire: convenience, a sense of vulnerability, particularly in patients with higher refractive errors, relief from tedious maintenance and handling procedures, and vocational and lifestyle issues. The widespread interest in refractive surgery since the 1980s underscores the appeal of a longer-term solution to refractive error. Marketing surveys agree that the recommendation of the practitioner is critical in determining the choice of correction. The industry, practitioners and patients alike have therefore keenly sought the development of a safe and effective EW contact lens.

For a detailed history of EW the reader is referred to Brennan and Coles (1997). Analysis of the early ventures in EW provides important clues as to the pitfalls with this wearing style. The current status of EW and its current format can be traced to the prominent aspects of this history.

Experiences with Extended Wear

The earliest report of EW appears to be a 1957 description of a non-compliant patient wearing an oxygen-impermeable polymethyl methacrylate (PMMA) contact lens continuously for 3 months. Details of a planned clinical trial were published in 1965, reporting on 50 patients wearing PMMA on a continuous-wear basis over a 7-year period (that is, without planned removal or replacement). Although such lenses have long since been condemned as unsuitable for EW, the absence of complications in these reports is noteworthy, and indicative of the resilience of the eye to sleeping in contact lenses.

CONVENTIONAL SOFT EXTENDED WEAR

The original soft lenses, designed for long-term repeated usage, are now referred to as 'conventional', 'traditional' or 'unplanned-replacement' hydrogel lenses to distinguish them from 'frequent-replacement' or 'disposable' lenses. Soft hydrophilic lenses were introduced around the world in the late 1960s and early 1970s as a result of the pioneering work of Wichterle. These lenses were very well received by the public, which was principally due to the comfort afforded. Contact lens sales promptly soared. But the inconvenience of caring for the lenses and the need to insert and remove them on a daily basis led to increased experimentation with extended periods of wear.

Early reports focused on the use of prolonged periods of wear for therapeutic use, particularly in aphakia. Perceived advantages included alleviation of the possible risks associated with removal and handling of lenses from diseased eyes and relief for patients with limited dexterity. The first material promoted for use in cosmetic EW was perfilcon A (Permalens™, CooperVision, Rochester, NY). It was suggested at the time that this could be worn continuously, day and night, for many months or even years (Efron et al., 2012).

Numerous studies of soft lens EW for cosmetic use soon appeared with encouraging results. The remainder of this chapter deals largely with EW lens usage for such a purpose. Following clearance by the US Food and Drug Administration (FDA) for cosmetic EW in 1981, a large proportion of contact lens prescriptions, particularly in the USA, were written for this purpose. An intense and exciting period of research followed during which many of the problems preventing complication-free EW were identified.

The reports of early clinical experiences with hydrogel EW lenses are too numerous to review here, but even a cursory review shows dramatic variation in quoted success rates. Such differences appear to depend upon patient selection, the type of lenses fitted, fitting approach (tight or loose), diligence of follow-up, and criteria used by investigators in assessing the severity of adverse reactions and in the categorization of success. For example, the study of Lamer (1983) reports a success rate as high as 81% following 3 years' EW compared with 48% reported by Binder (1983). Variation in study design remains a common problem in modern evaluation of EW success.

Despite the apparently low success rate, the retrospective study of Binder (1983) provides good insight into the success of these trials. This article reviewed over 1000 patients entered into a number of FDA regulatory studies of EW lenses, with intended wearing times of 2–4 weeks. As noted above, nearly half (48.5%) of patients 'survived' EW with only minor problems for 3.5 years. Of the discontinuations, almost a third (31.3%) of the subjects did so prior to beginning EW, 16.2% were lost to follow-up, 14.5% found lens comfort inadequate, and 12% experienced ocular complications. The frequency of individual complications was as follows: injection 3.7% (of the discontinued group), abrasion 1.6%, conjunctivitis 1.4%, contact-lens-related papillary conjunctivitis (CLPC) 1.4%, neovascularization 1.1%, dry eye, epithelial staining and oedema all less than 1%, and infections 0.2%.

The relative success observed in these trailblazing studies was quite astounding and provided considerable scope for optimism that relatively minor adjustments to the lens parameters would provide a safe, effective correction. By modern standards though, these studies used lenses and modalities that were grossly inappropriate for EW. The thick hydrogel lenses had oxygen transmissibility (Dk/t) levels that were later deemed to be inadequate. The period between lens removal was also up to 6 months in many of the early studies, and more recent research has arrived at the conclusion that this interval is too long for uncomplicated wear. But by far the greatest hazard with these early EW lenses was the emerging picture of severe complications due to infectious keratitis. A study conducted in the USA in 1987 and sponsored by the Contact Lens Institute (CLI) demonstrated that sleeping in contact lenses posed a significant risk over and above that of contact lens wear alone (Poggio et al., 1989). The adverse publicity subsequent to publication of this study meant that EW usage decreased dramatically during the 1990s.

NON-HYDROPHILIC MATERIALS

The high oxygen permeability (Dk) of silicone elastomer led to interest in using this material for extended contact lens wear. In the late 1970s, a number of fitting trials were undertaken. Unfortunately, the hydrophobic nature of the lens surface resulted in poor wetting and surface deposition (Fig. 24.1). The highly elastic nature of the material and resistance of the material to water permeation also brought about lens binding. These factors prevented the success of this material except for limited use in paediatric and aphakic fitting.

Towards the mid 1980s, rigid gas-permeable materials became a popular alternative to hydrogels for EW, the principal attraction being a higher Dk/t without the adverse properties of silicone elastomer. Other perceived advantages of rigid lenses over hydrogel lenses include a higher rate of tear exchange beneath these lenses, less corneal coverage and a more inert lens surface.

A considerable body of literature provided evidence for successful EW in patients using these lenses (Maehara and Kastl, 1994). Certainly, preclinical evaluations confirmed that rigid lenses produced fewer oxygen-related physiological changes, such as corneal oedema, than hydrogels. However, there remained a range of limitations with rigid lenses for EW. Complications found with hydrogels, such as infectious keratitis, infiltrative keratitis and CLPC, were not eliminated. The elevated risk of infectious keratitis caused by sleeping in contact lenses observed with hydrogels was also evident with rigid lenses (Macrae et al., 1991). As well, rigid lenses induce a greater degree of initial discomfort than hydrogels and complications largely unseen with hydrogels, such as 3 and 9 o'clock staining, corneal distortion and lens binding.

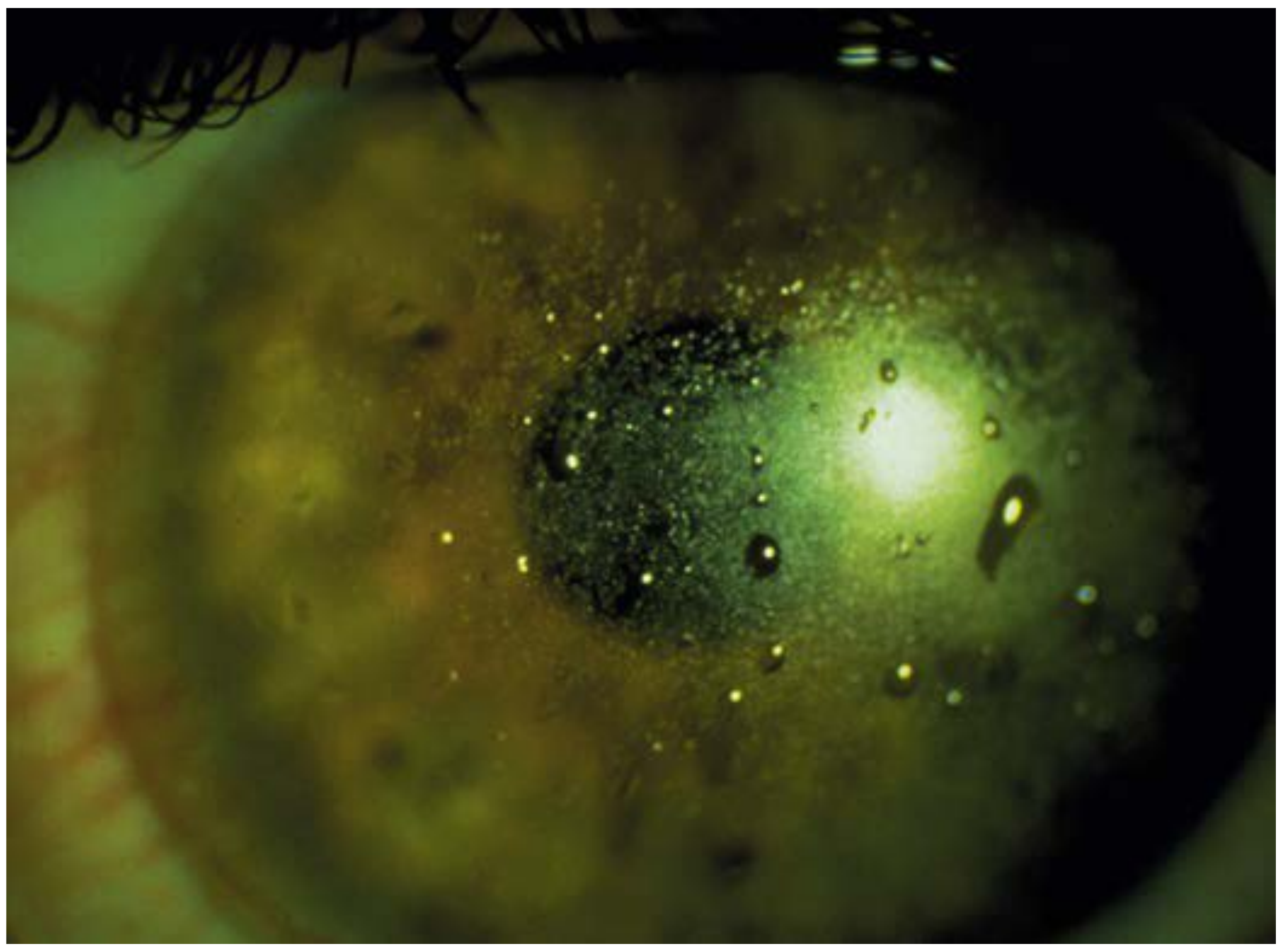
Fig. 24.1 A silicone elastomer lens displaying poor wetting. (Courtesy of Timothy Grant, Bausch & Lomb Slide Library.)

Most practitioners have been unwilling to devote the additional time required to achieve a suitable fit and deal with patient complaints of discomfort, so rigid lenses are nowadays rarely fitted for traditional cosmetic EW. However, overnight wear of rigid lenses to achieve temporary reversal of refractive errors, known as orthokeratology, maintains a fervent, if specialized, following and has become a specialty area of contact lens practice (Chapter 32).

DISPOSABLE SOFT LENSES

Efficiencies of manufacture allowed Johnson & Johnson Vision Care (Jacksonville, FL) to bring low-cost disposable lenses made of etafilcon A material (Acuvue®) to the US market in 1987. The original intention was that the lenses be worn continuously for 1 week at a time. At the end of each week, the lenses were to be discarded and replaced by a new set of lenses. In essence, this was a simultaneous launch of the concepts of weekly EW and lens disposability (Efron et al., 2012).

Frequent replacement of lenses offers a range of potential advantages for increasing EW success. Practitioners perceived that the most significant problem with conventional hydrogel lenses was the build-up of surface deposits and associated complications, such as CLPC (Orsborn and Zantos, 1989). Frequent replacement restricts exposure of the eye to accumulated aged or denatured protein, which seems to act as an antigen in inducing inflammatory reactions such as CLPC and infiltrative keratitis. Control of deposit build-up by frequent replacement has the further advantage of reducing patient symptoms related to vision and comfort.

While reducing exposure of the eye to lens deposition is the outstanding advantage of disposable lenses, the regular provision of fresh, clean lenses also showed promise in other areas. There was hope that frequent lens replacement would lead to fewer bacteria being introduced to the eye, thereby reducing the risk of infectious keratitis during EW. In regard to lens maintenance, disposability offers simplification of cleaning procedures, easier lens fitting and replacement, and may serve to enhance patient compliance.

In practice, the benefits with respect to ocular physiology, symptomatology and convenience are compelling, and replacement of lenses every day to every 2 weeks to 1 month now predominates contact lens prescribing around the world (Morgan et al., 2016). Clinical studies have certainly confirmed that frequent replacement reduces the occurrence of inflammatory events during EW. Both non-infectious corneal infiltrative events and CLPC show reduced incidence with more frequent replacement. However, these complications are not entirely eliminated, as will be discussed further below.

The early enthusiasm for prescribing EW with disposable hydrogel lenses was not maintained. Although the CLI-sponsored study was restricted to conventional replacement contact lenses, damage to the reputation of EW had been done (Poggio et al., 1989; Schein et al., 1989). A number of publications reported on corneal infections in association with frequent-replacement lenses. Academics and educators delivered widespread warnings of the potential complications of EW. By and large, practitioners around the world fell in line and EW prescribing dropped to very low levels globally by the end of the 1990s.

Moreover, despite the apparent benefits and contrary to the hopes and expectations of the contact lens industry, frequent contact lens replacement failed to achieve the desired impact on the rate of infectious keratitis. Reports in the early 1990s suggested that the frequency of infections with disposable lenses was equal to or even greater than that with conventional replacement. In a nationwide survey of ophthalmologists in the Netherlands in 1996, Cheng et al. (1999) demonstrated that rates of infection with disposable lenses, in both daily and EW, were essentially the same as those observed in the CLI study (Poggio et al., 1989). Despite the significant advantages offered by disposability, it was evident that the industry had to look elsewhere for answers to the challenge posed by infectious keratitis with EW.

SILICONE HYDROGEL CONTACT LENSES

With the failure of frequent-replacement hydrogel lenses to solve the EW infection problem and persistent physiological compromise to the cornea during closed eye wear, the industry turned its attention to the development of materials with high Dk. In the late 1990s, silicone hydrogel (SiHy) contact lenses were introduced to the market. The details of the advances incorporated in these materials are presented in Chapter 4. In brief, the high Dk and good handling characteristics of silicone are combined with the flexibility and comfort of hydrophilic materials. Considerable advances in technology over previously manufactured lenses were required to combine these two ostensibly incompatible materials, not the least of which was new technology to produce a wettable, deposit-resistant surface. The early lenses used plasma surface coatings, but later generations of lenses managed to circumvent the need for this additional manufacturing step.

Clinical research demonstrated that EW of SiHy lenses produce fewer physiological changes, such as microcysts, corneal striae and endothelial blebs and less limbal and bulbar conjunctival injection, than did hydrogel lenses (Covey et al., 2001; Brennan et al., 2002; Inagaki et al., 2003; Radford et al., 2009). These benefits arise from the lowered resistance of the materials to oxygen flow. SiHy lenses may also, on occasion, provide the added benefits of less corneal staining, less subjective dryness and discomfort, and better handling, owing to properties such as hydration, modulus, surface and design characteristics.

These advantages of SiHy lenses were quickly recognized and some countries such as Australia, which had previously shunned EW, enthusiastically adopted these new materials. Other countries such as the USA and the UK, following failure of the EW foray of the 1980s, were more cautious in approach. Nonetheless, by 2003 some 10% of all contact lens fits worldwide were for EW (Efron et al., 2012).

Although the increased corneal oxygenation afforded by SiHy lenses virtually eliminated physiological or metabolic corneal disorders during EW, epidemiological studies revealed that, despite the hopes of the contact lens community, there was little impact on corneal infection rates (Morgan et al., 2005; Schein et al., 2005; Dart et al., 2008; Stapleton et al., 2008). As a result, the fitting of EW in practice remained at no more than about 10% globally until 2007 and had declined to around 8% by 2015 (Morgan et al., 2016) (Fig. 24.2). Nonetheless, the vast majority of EW fits are in SiHy materials (Fig. 24.3). There remain pockets of devotees to EW, with countries such as Norway, Lithuania and Sweden continuing new fits into EW in high numbers.

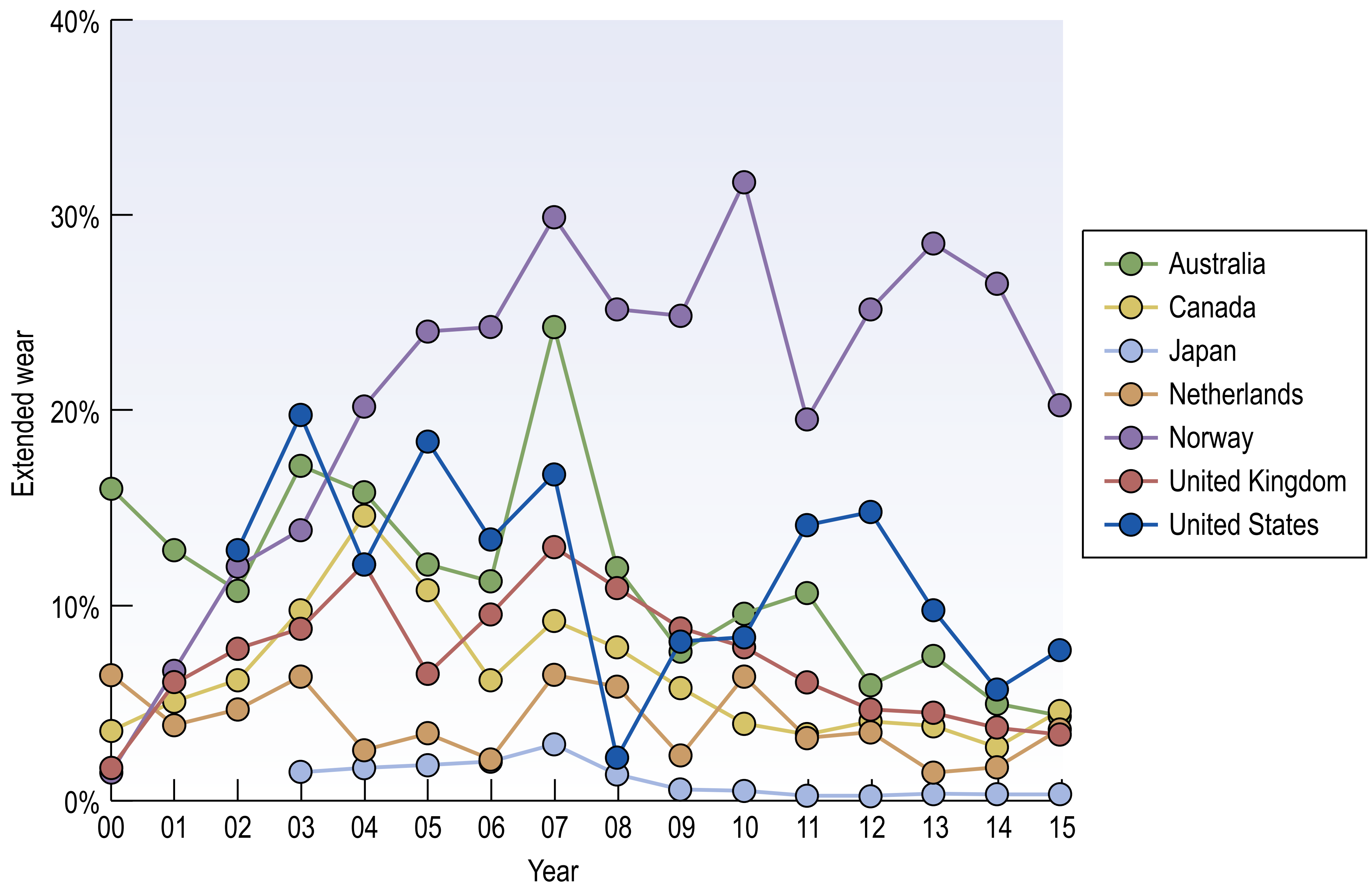

Fig. 24.2 Extent of extended wear soft contact lens fitting as a percentage of all soft lenses prescribed in seven nations between 2000 and 2015.

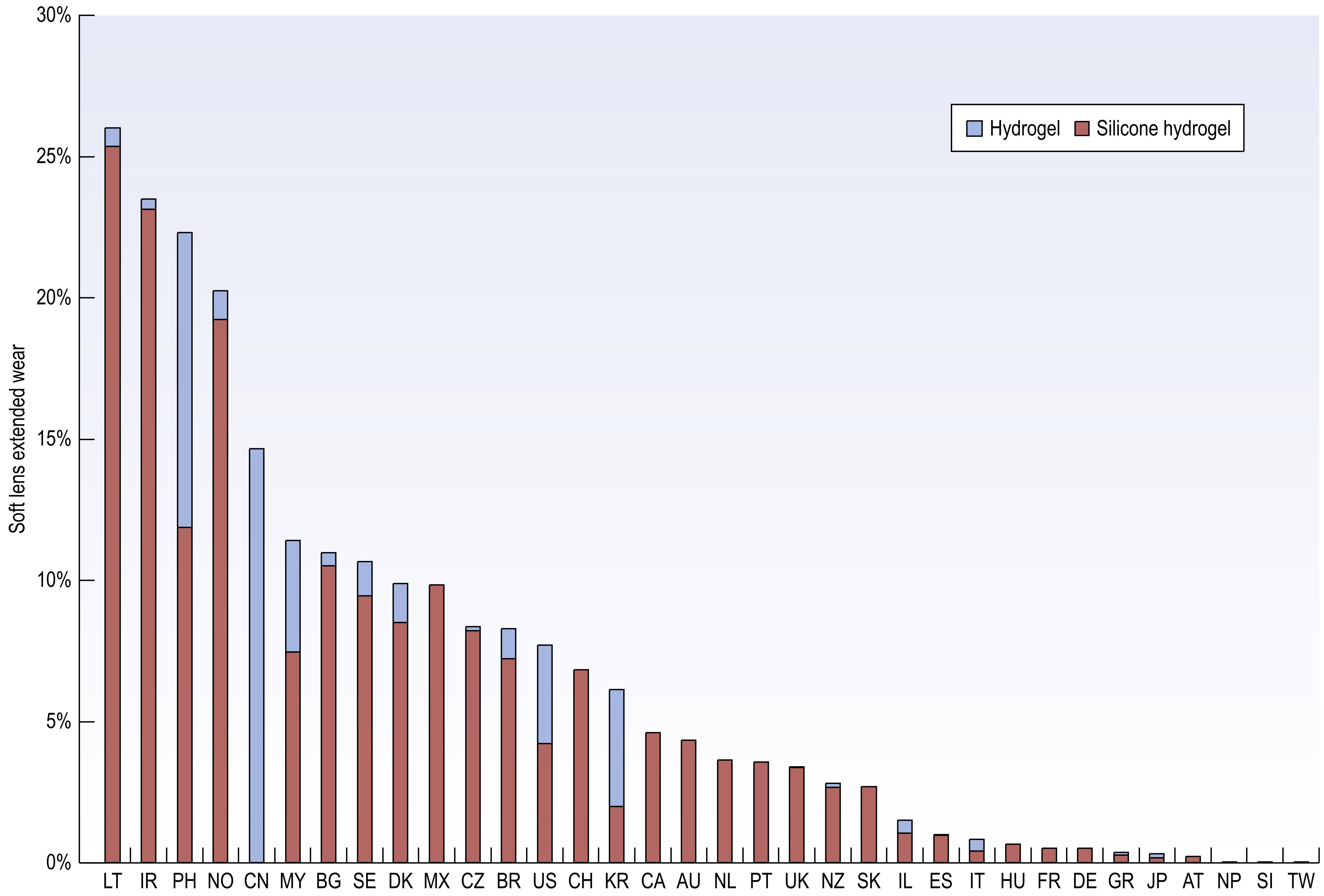

Fig. 24.3 Extended wear soft contact lens fits as a proportion of all soft lens fits in 34 nations in 2015. Country codes: AT= Austria; AU= Australia; BG = Bulgaria; BR= Brazil; CA= Canada; CH= Switzerland; CN= China; CZ= Czech Republic; DE= Germany; DK= Denmark; ES= Spain; FR= France; GR= Greece; HU= Hungary; IL= Israel; IR= Iran; IT= Italy; JP= Japan; KR= Korea; LT= Lithuania; MX= Mexico; MY= Malaysia; NL= Netherlands; NO = Norway; NP= Nepal; NZ= New Zealand; PH= Philippines; PT= Portugal; SE= Sweden; SI= Slovenia; SK= Slovakia; TW= Taiwan; UK= United Kingdom; US= United States.

SUMMARY

As Efron et al. (2012) explain, EW prescribing 'has failed to break through the "glass ceiling" of 15% and is unlikely to become a mainstream lens-wearing modality until the already low risks of ocular complications can be reduced to be equivalent' to those for daily wear. In particular, a continued EW microbial keratitis rate of around 20 per 10 000 wearers per year is considered problematic. The industry is in need of further breakthroughs, say for example the commercial release of lenses with antimicrobial activity, before we are likely to see substantial expansion of the EW market.

Adverse Effects of Extended Wear

The presence of a contact lens on the eye brings with it a number of potential adverse responses. This is the case whether the lens is worn on a daily-wear or EW basis. A detailed discussion of adverse events with contact lens wear is provided in Chapter 40. Some specific events are more prevalent during EW and these are presented below. The main feature of this discussion is to analyse the mechanisms of the ocular changes and to review risk factors and strategies to minimize these effects. Table 24.1 summarizes the major risk factors for complications with EW and these, as well as methods for mitigating the impact, are discussed in more detail below. Other issues common to daily-wear contact lenses, such as corneal staining, discomfort and the symptom of dryness, remain important in EW, but are dealt with elsewhere in this book.

INFECTIOUS CORNEAL ULCERATION

Infectious corneal ulceration (Fig. 24.4) occurs with higher frequency in contact lens wearers than in non-lens-wearers, and those who sleep in their lenses are at a higher risk than those who wear their lenses on a strictly daily wear basis (that is, never sleeping with lenses in). The infection can lead to tissue necrosis and massive inflammation. Pseudomonas and Serratia species are the more commonly isolated bacteria from infectious corneal ulcers in EW patients. The incidence of infection by other microbial species such as fungi and Acanthamoeba may be higher in contact lens wearers but there is no specific evidence to suggest a heightened risk with EW. Although viral and chlamydial keratoconjunctivitis may also occur in contact lens wearers, there is no elevated risk apparent with the wearing of contact lenses.

Microbial keratitis can cause severe pain, photophobia and distress and, in some cases, vision loss. With early hydrogel EW, such problems were sensationalized by the lay press and numerous cases of legal action were initiated. The reported success of the early trials in the light of later reports of a raised incidence of infectious keratitis with EW is not surprising given the rarity

TABLE 24.1 Risk Factors for Infectious, Inflammatory and Physiological Changes Identified in Clinical and Epidemiological Studies

Risk Factor	Effect*	Remedy
MODIFIABLE RISK FACTORS		
Sleeping in lenses	1,2,3	Do not sleep in lenses
Long periods (>6 nights) between removal	1,2	Reduce duration of EW
Long periods between lens replacement	2	Fit disposable lenses of greater replacement frequency
Hot climates	1,2	Education and reinforcement; consider daily disposables if on vacation
No / poor handwashing	1,2	Education and reinforcement of hygiene and care of lenses
Poor care and maintenance	1,2	Education and reinforcement of hygiene and care of lenses
Poor storage case hygiene	1,2	Frequent case replacement, education and reinforcement
Smoking	1,2	Counsel on increased risks
Work environment	1,2	Reduce exposure to ocular irritants, use eye protection, counsel on risks
Topical steroid therapy	1	Suspend EW until therapy completed
Internet purchase	1,2	Education on importance of regular examinations, regular review, reinforcement of hygiene and care of lenses
Tightly fitting lenses	2,3	Fit more mobile lenses
Low Dk/t	3	Fit SiHy lenses
SiHy lens wear	2	Fit hydrogel lenses
NON-MODIFIABLE RISK FACTORS		
Male gender	1,2	Use discretion in prescribing; counsel on increased risks
Age (12–25 years)	1,2	Use discretion in prescribing; counsel on increased risks
Diabetes	1,3	Use discretion in prescribing; counsel on increased risks
Early period of EW	1,2	Use discretion in prescribing; counsel on increased risks

*1 = risk of microbial keratitis; 2 = risk of corneal infiltrative events (CIEs); 3 = risk of physiological disturbance.

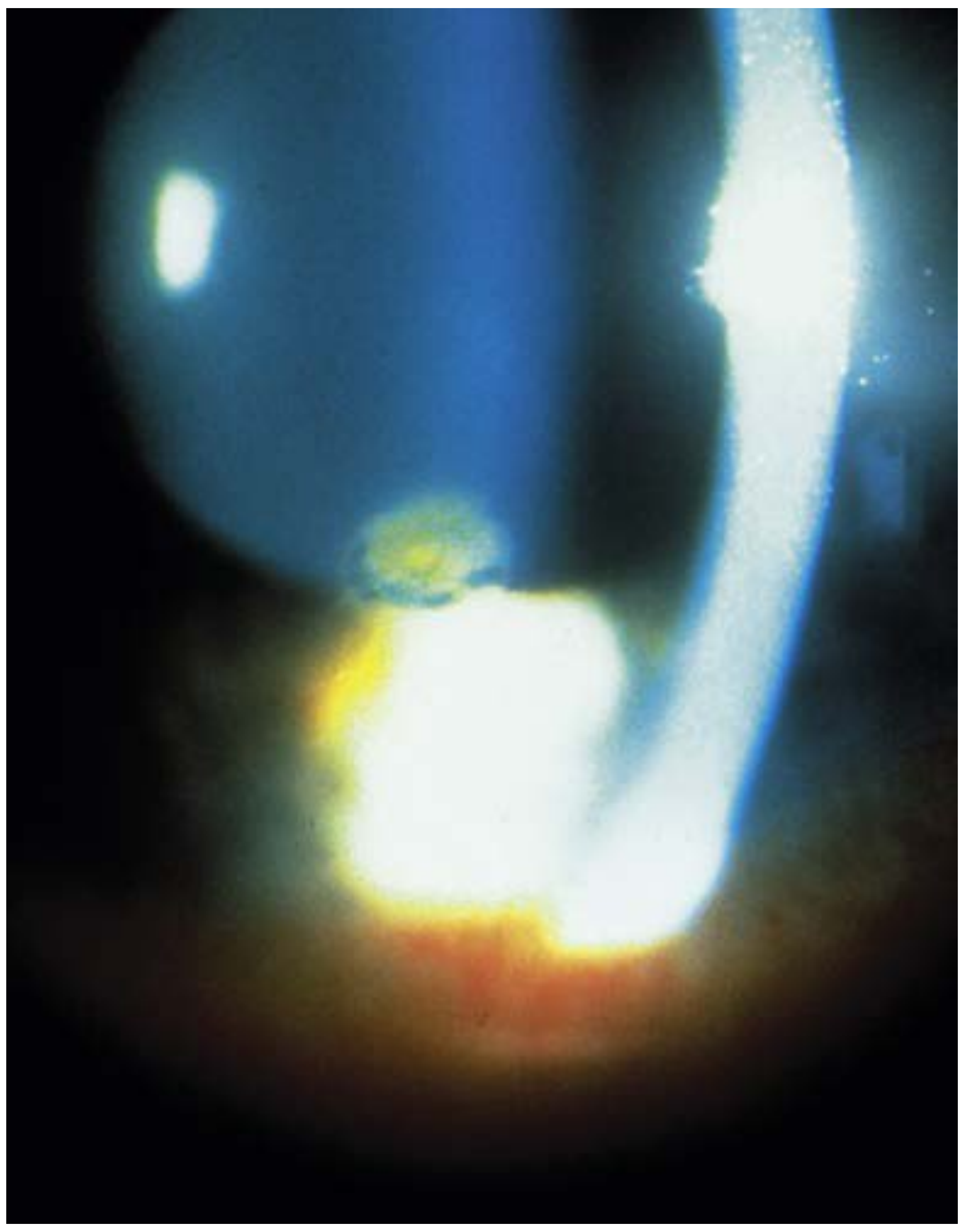

Fig. 24.4 Microbial keratitis is the most concerning feature of extended contact lens wear. This picture shows a Pseudomonas infection. (Courtesy of Lyndon Jones, Bausch & Lomb Slide Library.)

of infection. Despite this low incidence, the large number of people adopting EW led to a disturbingly high frequency of hospital admissions with contact-lens-related infections. This concern came to the attention of authorities, who described it as a 'significant, preventable, public health problem.'

The major epidemiological study sponsored by the CLI, as mentioned above, determined that the incidence of clinically diagnosed infectious keratitis for daily-wear and EW hydrogel lenses was approximately 4 and 20, respectively, per 10 000 wearers per year (Poggio et al., 1989). Subsequent studies have found similar estimates for the incidence of microbial keratitis, confirming that EW entails a higher relative risk than does daily wear of hydrogel materials, regardless of whether lenses are worn in disposable or conventional mode, and whether they are hydrogel or SiHy lenses (Cheng et al., 1999; Morgan et al., 2005; Schein et al., 2005; Dart et al., 2008; Stapleton et al., 2008). These epidemiological studies and other case reports have highlighted a number of risk factors for keratitis with extended contact lens wear (see Table 24.1).

The precise pathogenesis of contact-lens-related microbial keratitis remains elusive. The large-scale field experiments of frequent replacement of lenses and use of SiHy materials tested whether corneal lens spoliation and hypoxia were important mechanisms of corneal infection. Neither advance 'moved the needle' with respect to the apparent rate of EW infection. Recent research implicates changes in virulence factors of P. aeruginosa on prolonged exposure to the ocular environment and decay in the antimicrobial activity of the post-lens tear fluid during lens wear as important aetiological factors (Tam et al., 2010; Wu et al., 2015).

NON-INFECTIOUS INFLAMMATORY EVENTS

While infectious keratitis is most often cited as the reason for failure of EW in the 1980s, the high incidence of 'non-infectious' corneal inflammatory events probably contributed strongly to practitioner aversion to this mode of wear. Corneal inflammation is characterized by the migration and accumulation of inflammatory cells into the epithelial and anterior stromal space. Such events are collectively termed 'corneal infiltrative events' (CIEs). These events may or may not be symptomatic. Although CIEs are not sight threatening, they constitute a sufficiently acute response to cause interruption or even termination of EW. Indeed, the Food and Drug Administration of the USA has used CIEs as a surrogate measure of the safety of contact lenses in pre-market-approval studies for 30-day continuous

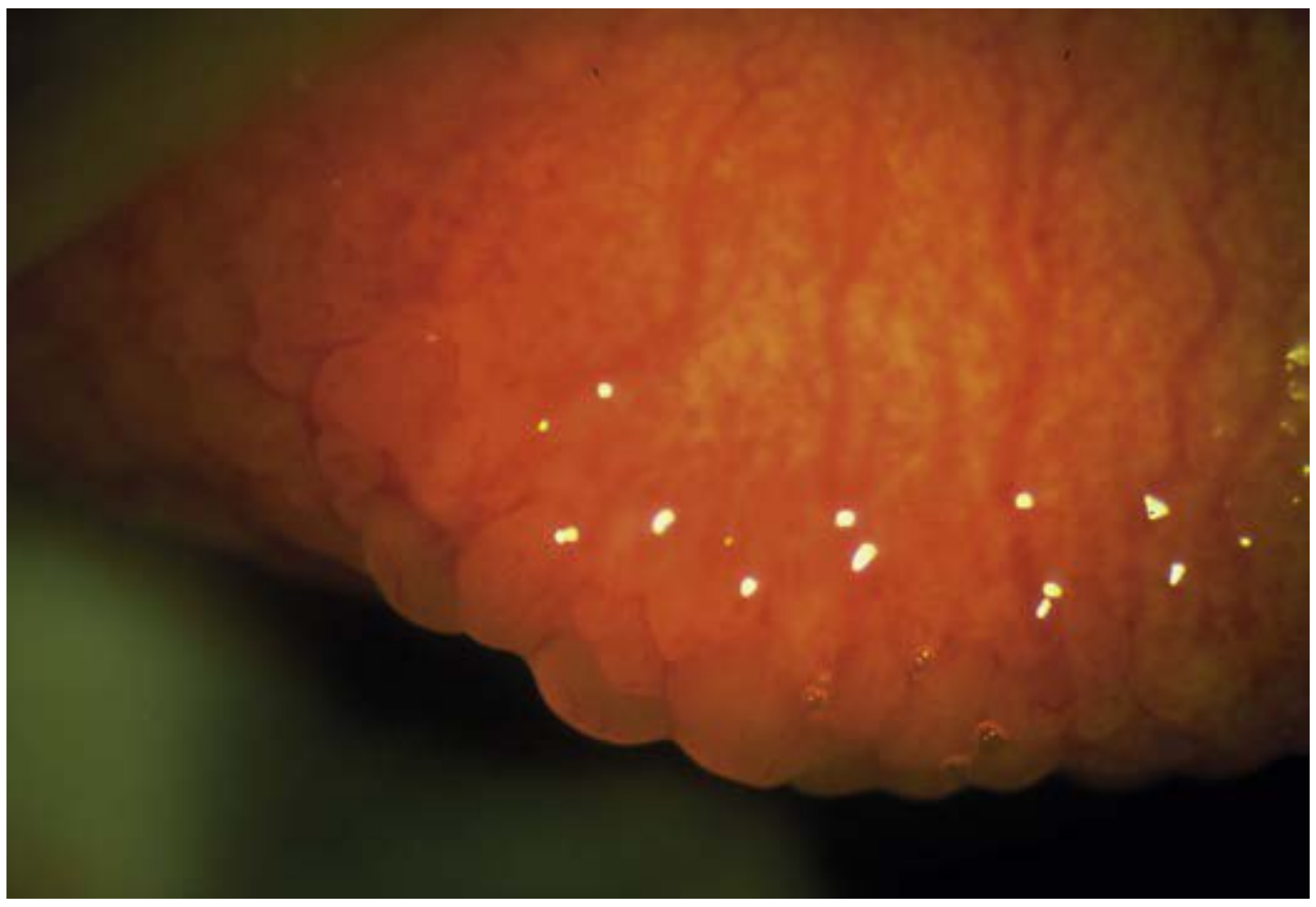

Fig. 24.5 Both mechanical and hypersensitivity responses to lens deposits can lead to contact-lens-related papillary conjunctivitis. (Courtesy of Maki Shiobara, Bausch & Lomb Image Library.)

wear, as the low incidence of infectious keratitis makes measurement of the rate impractical in trials of new lens materials.

CIEs pose a considerable challenge for clinicians and researchers alike with respect to diagnosis and classification and these are discussed in more detail below. The principal concern is to separate those incidents that are truly infectious, caused by virulent organisms, likely to progress and in need of urgent intensive treatment from those that are apparently sterile or caused by less virulent organisms, self-limiting and in need of no or minimal treatment.

Although a cornea may not suffer frank infection during a so-called 'sterile' inflammatory keratitis, there remains considerable circumstantial evidence that at least some of these events are due to the presence of bacteria and their exo- and endotoxins at the corneal surface. Strategies that minimize the bacterial load at the corneal surface may therefore help reduce the risk of CIEs.

During EW, the incidence of symptomatic CIEs has been found to be between about 2.5–6% per year while inclusion of asymptomatic events raises this range to 6–26% per year. EW of contact lenses causes some two to four times increased risk of CIEs compared with daily wear. The wide range of values for rates of CIEs probably arises from differences in experimental designs. Prospective studies with more frequent subject visits certainly show higher rates of asymptomatic CIEs. A series of studies following the introduction of SiHy lenses with large sample sizes has shown a consistent doubling of the rate of CIEs with these lenses compared to hydrogel lenses (Szczotka-Flynn and Chalmers, 2013). This finding seems to be consistent across wearing modalities. We hypothesize that this may relate to the ability of hydrogel lenses to attract and retain non-denatured protein to the lens surface, which may provide both antibacterial and immunogenic advantages.

Another inflammatory condition, contact lens-related papillary conjunctivitis (CLPC) (Fig. 24.5) was also a principal hindrance to successful EW with early hydrogel lenses. As noted above, use of frequent-replacement contact lenses helped to lessen the incidence of the condition with hydrogels. However, the introduction of first-generation high-modulus SiHy lenses that were intended to be worn continuously for 30-day periods saw the re-emergence of CLPC as a significant complication of contact lens wear. This chronic inflammatory reaction of the palpebral conjunctiva resembles vernal conjunctivitis but is directly related to contact lens wear (see Chapter 40 for more details). Both mechanical and antigenic stimuli are implicated as causative agents. Thus CLPC can be controlled in part by using lenses with a more frequent replacement schedule, a lower modulus and a lower surface coefficient of friction.

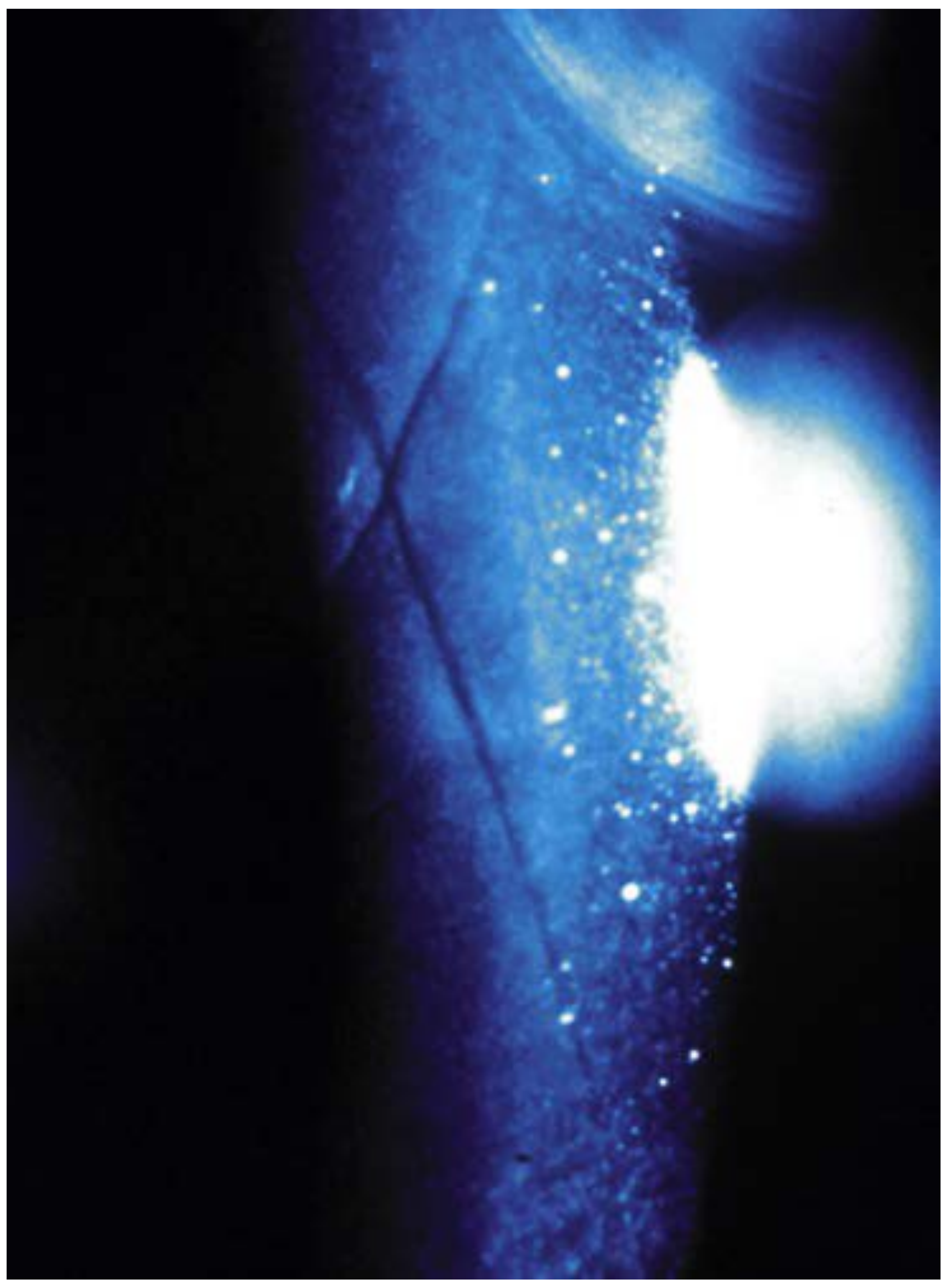

Fig. 24.6 Folds observed in the posterior stroma following overnight wear of lenses of low to medium Dk/t. (Courtesy of Steve Zantos.)

ACUTE PHYSIOLOGICAL EFFECTS

When worn during eye closure, hydrogel lenses induce corneal oedema, which is observable clinically on awakening as striae and folds (Fig. 24.6). The effects persist for some time following eye opening, and in some cases throughout the day. In some circumstances, visual disturbance, in the form of haze and blur, is noted. Although the acute effects on corneal oedema resolve rapidly, wearing a hydrogel contact lens in EW produces a recurring pattern of oedema during the night followed by partial resolution during the day (Holden et al., 1983). Chronic exposure to this unfavourable environment is considered by some to be detrimental to long-term corneal health.

The short-term corneal oedema response has been the gold standard for assessing the physiological challenge posed by a contact lens to the eye and it has consequently been a favourite area of investigation for researchers in the contact lens field. Understanding factors influencing this response potentially enables the practitioner to avert long-term adverse physiological effects. Interpretation of corneal swelling data relies on comprehension of the expression of measurement, and some standards against which this can be compared. Typically, corneal oedema is expressed as a percentage swelling from baseline corneal thickness, which is usually and perhaps inappropriately measured as the thickness of the cornea prior to sleep.

Since the cornea that is unadapted to contact lens wear swells by approximately 4% centrally overnight, this value has been suggested as a criterion for the safe maximum level of oedema in response to overnight contact lens wear (Holden et al., 1983). Fig. 24.7 plots this value against some of the yardsticks for evaluating oedema effects, and Fig. 24.8 gives the average corneal swelling for a range of different lens types.

These values are for central corneal swelling, but the cornea does not swell uniformly. Figs. 24.9–24.11 plot the topographical corneal swelling for three different lens types. In each circumstance, the temporal and nasal mid-peripheral cornea swell more than the central cornea. It is apparent from Figs. 24.10 and 24.11 that SiHy lenses provide near-normal levels of oxygen to the cornea during sleep, where hydrogel lenses fail to do this. Given the ability of SiHy lenses to meet the needs of the cornea in this regard, other previously suggested criteria for acceptable levels of overnight oedema should be abandoned.

Not all corneas exhibit the same baseline thickness, and not all corneas swell by the same amount in either relative or absolute terms. Fig. 24.12 plots the absolute change in corneal thickness measured on two separate occasions versus the baseline central thickness for 15 subjects wearing thin, medium-water, hydrogel lenses. This graph demonstrates intersubject variability in both baseline thickness and the extent of swelling. While variation in swelling between subjects is probably determined by a complex combination of anatomical and functional factors – such as endothelial cell density – one additional prominent feature seems to be the level of adaptation to contact lens wear. The cornea of a subject adapted to daily wear of hydrogel lenses swells by 2% less than observed in an unadapted wearer, with adapted extended wearers swelling less by a further 1% (Cox et al., 1990). The relative roles of adaptation versus residual swelling in this effect are open to some interpretation. Nonetheless, this observation may in part explain some of the variation in different reports for mean swelling results to the same stimulus. For example, estimates of the closed-eye swelling

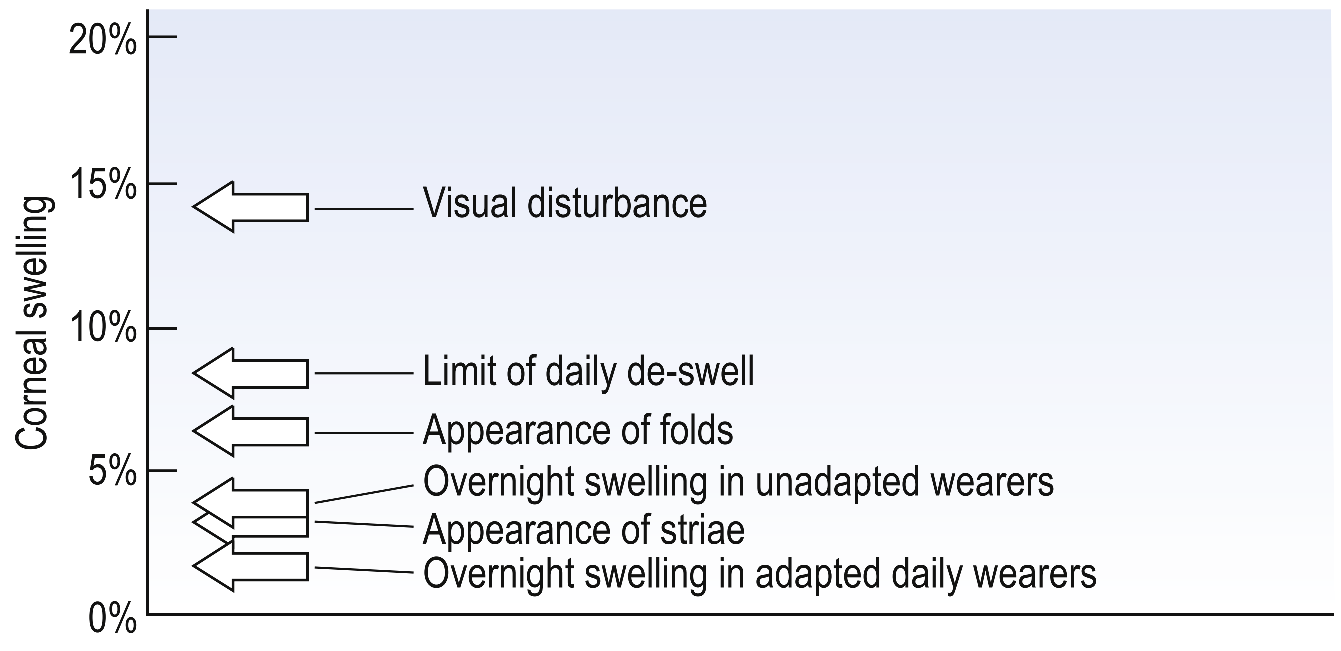

Fig. 24.7 Guide for assessing the impact of oedema in extended wear.

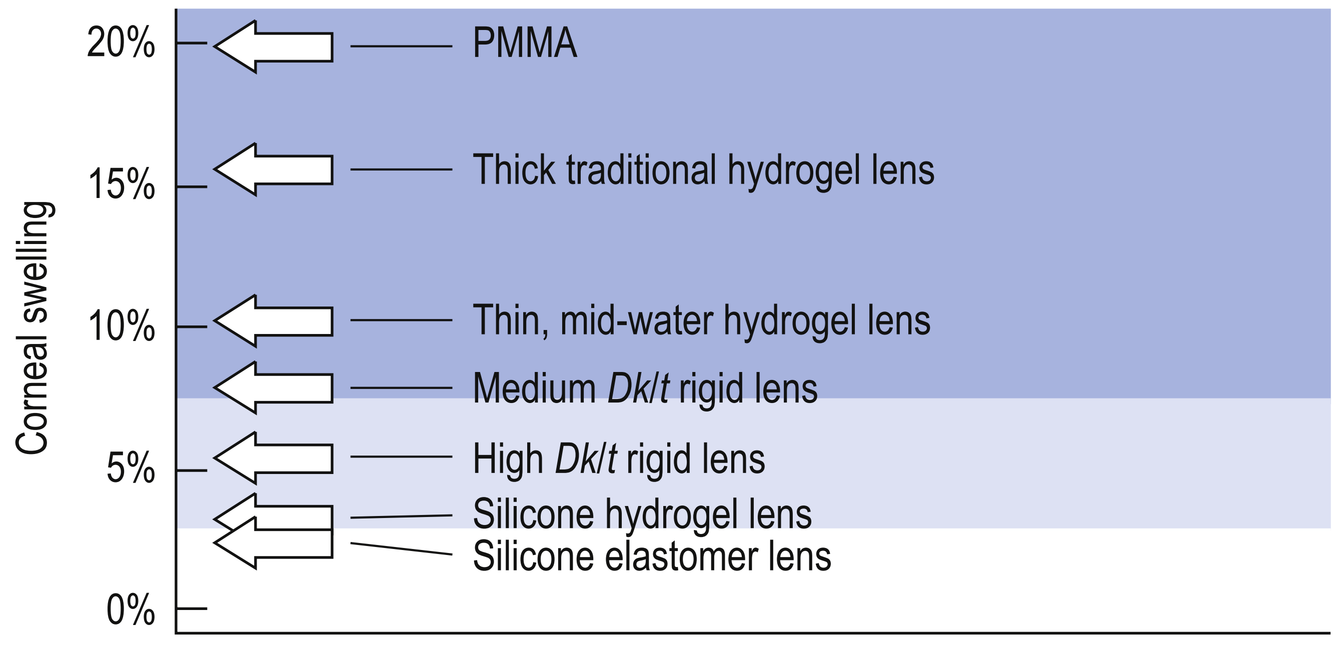

Fig. 24.8 Representative overnight corneal swelling in response to different lens types. PMMA = polymethacryl methacrylate.

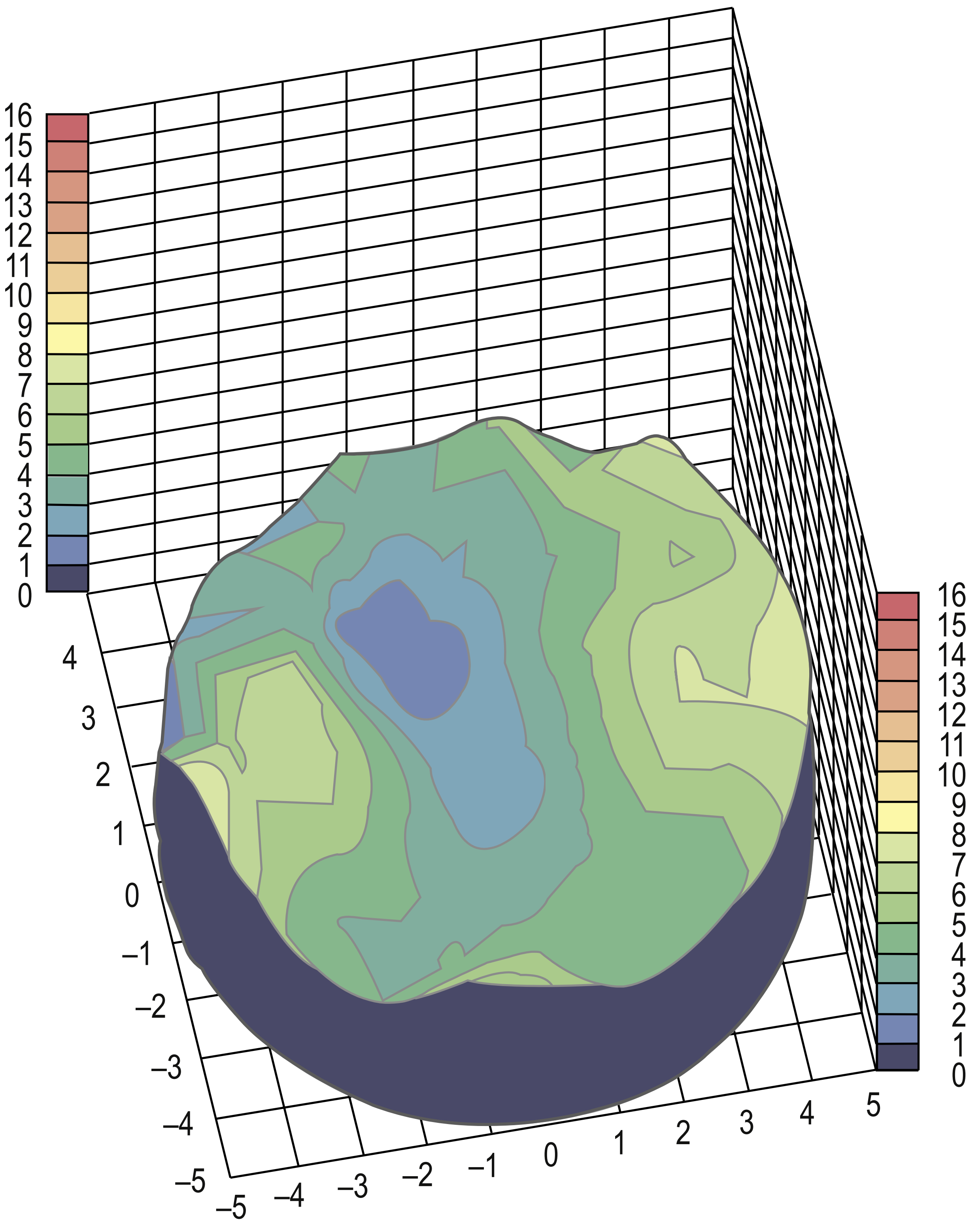

Fig. 24.9 Three-dimensional representation of average topographical corneal oedema response to wear of silicone elastomer lenses under closed-eye conditions. To the right is the nasal direction, and the closer region is the inferior cornea.

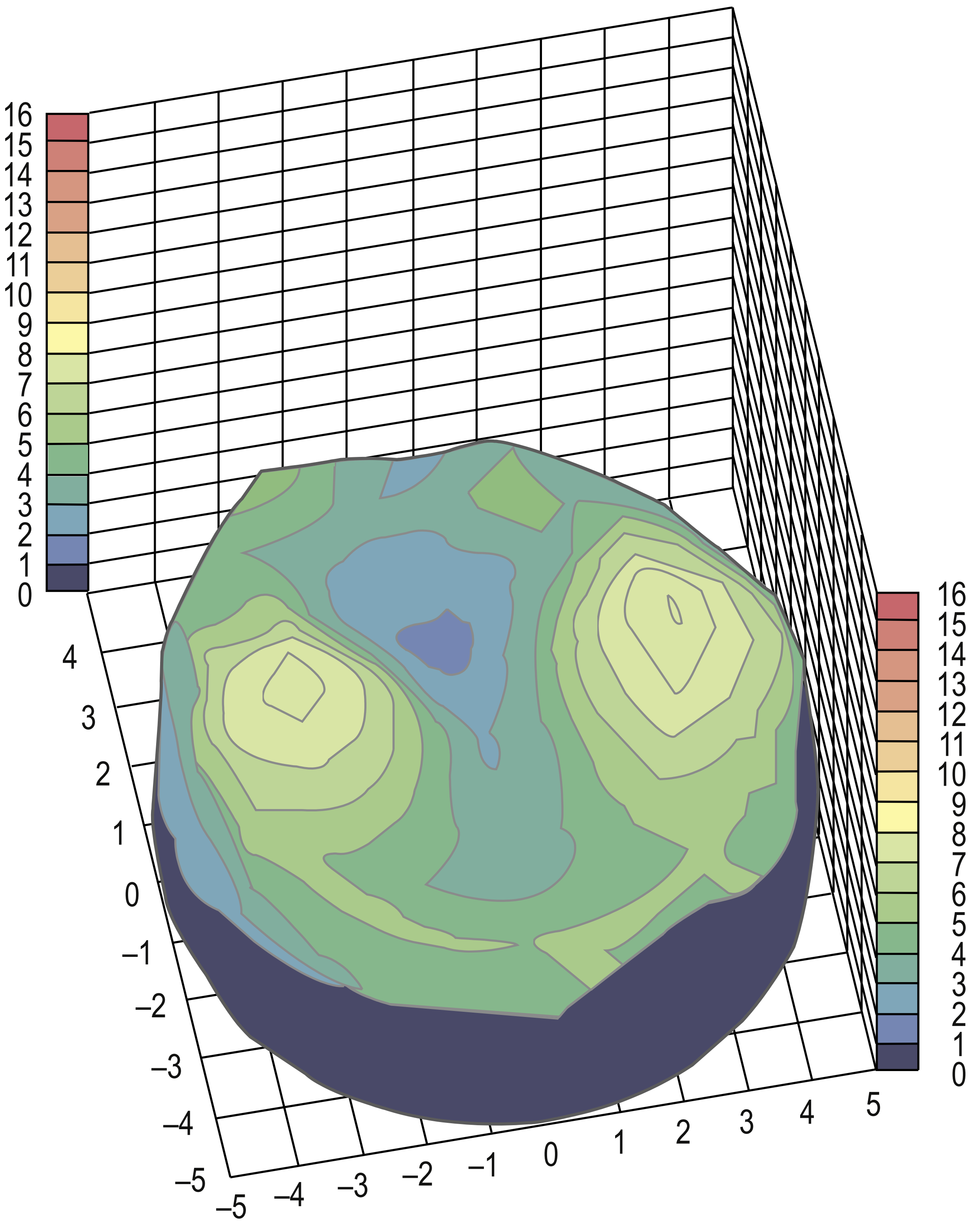

Fig. 24.10 Three-dimensional representation of average topographical corneal oedema response to wear of SiHy contact lenses under closed-eye conditions. To the right is the nasal direction, and the closer region is the inferior cornea.

response in the absence of a contact lens vary between 1.0 and 5.5%, a result that can be traced in part to the adaptation levels of the subjects. The criterion for the maximum acceptable level of overnight corneal swelling should be viewed in the context of this finding. If the baseline for contact lens corneal-swelling studies is taken as the corneal thickness upon awakening without overnight lens wear, then apparent variation between individuals and adaptation levels is substantially reduced.

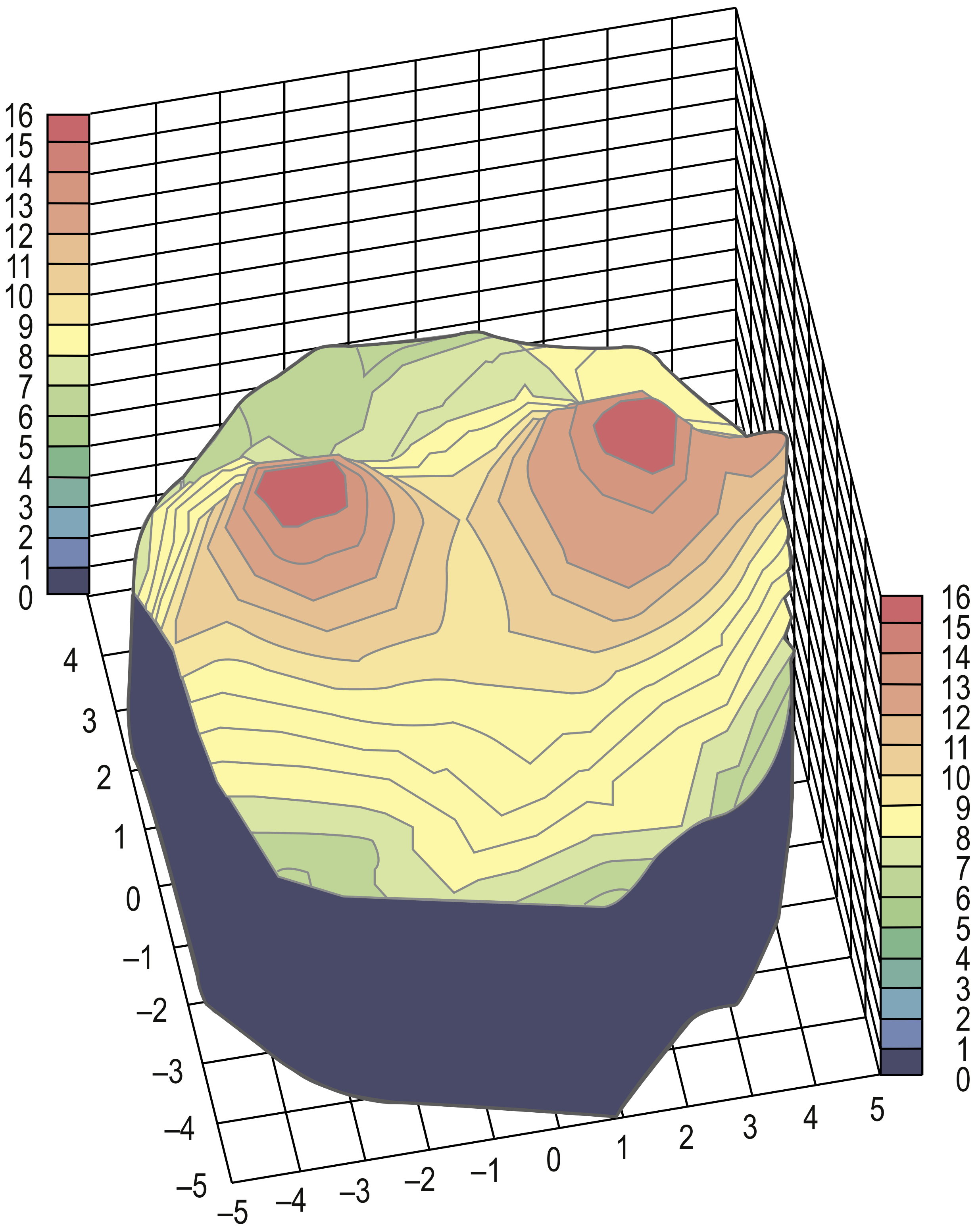

Fig. 24.11 Three-dimensional representation of average topographical corneal oedema response to wear of a mid-water hydrogel lens under closed-eye conditions. To the right is the nasal direction, and the closer region is the inferior cornea.

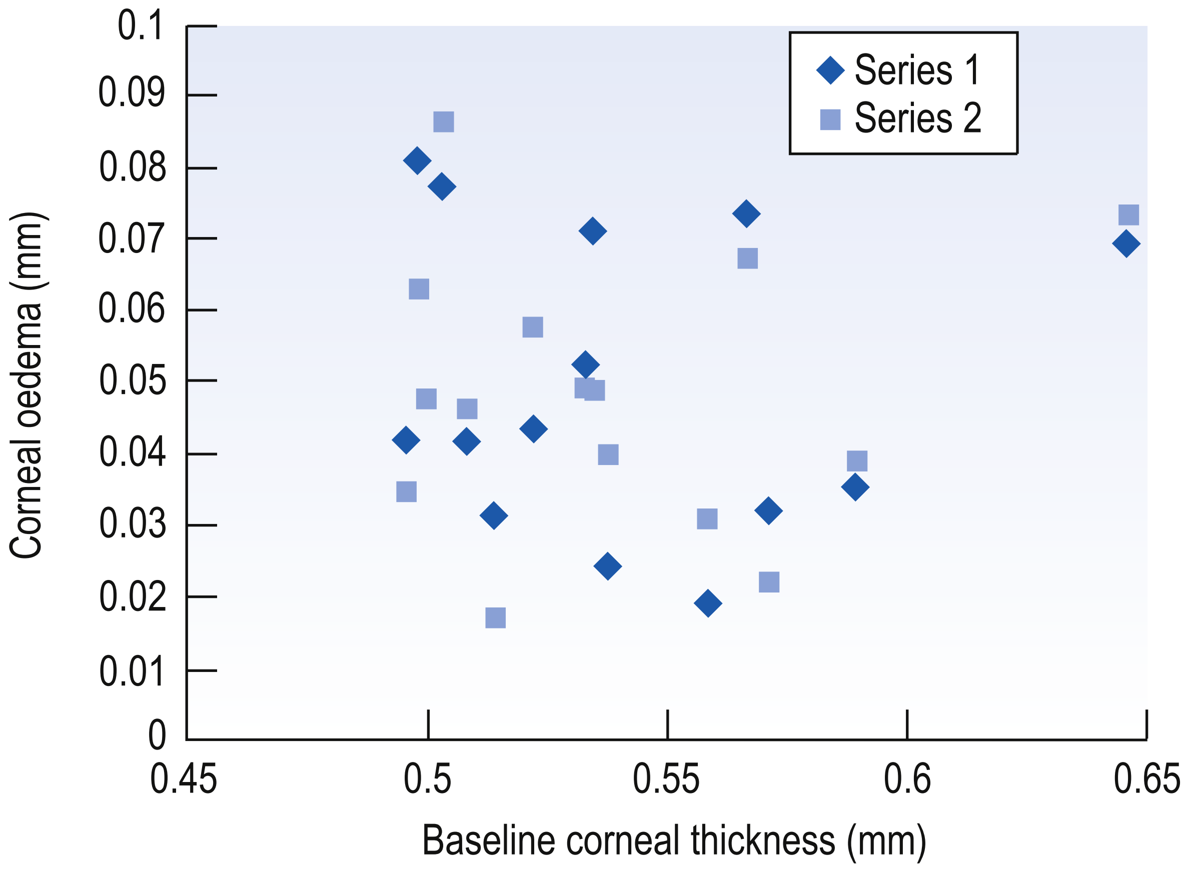

Fig. 24.12 Overnight central corneal swelling of 15 subjects on two occasions (Series 1 and 2) with wear of a mid-water hydrogel lens. Individual baseline thickness variability is demonstrated by variation along the x-axis, and individual swelling differences are shown by the variation along the y-axis.

Differences in corneal swelling between subjects are of unknown consequence. One study has suggested that subjects prone to higher amounts of oedema are more likely to discontinue lens wear and experience adverse ocular findings (Solomon, 1996). Another study found no effect, in that subjects experiencing infiltrative keratitis show the same degree of swelling as do subjects without complications (Stapleton et al., 1998). An opposite argument can be proposed – that the cornea adapted to EW, which shows the least amount of swelling, has a reduced metabolic rate and thus has less healing capacity and lower reserves for defence against potential threats. Thus, the patient with a cornea that shows a high degree of swelling might be more prone to contact lens intolerance, but at the same time may be more resilient to threats against corneal health. Further research is needed to resolve this question.

THE ROLE OF HYPOXIA

The principal factor causing corneal swelling during overnight lens wear is hypoxia (Holden and Mertz, 1984). A decrease in oxygen concentration within the corneal epithelium leads to anaerobic metabolism, of which the principal by-product is lactate. Accumulation of lactate within the stroma creates an osmotic pressure gradient into the cornea and also has the effect of lowering pH. Temperature, tear osmolarity and tear pH may also vary under the closed eye, but such variances contribute only a small amount of the overall oedema response.

One way of assessing the oxygen flow through a contact lens is by measurement of its Dk/t (see Chapter 4). This laboratory-derived figure gives an in vitro indication of the likely impact of a lens on the eye and has become an industry standard. Certainly, the amount of swelling that occurs in a cornea can be roughly related to the Dk/t of the lens (Fig. 24.13).

Holden and Mertz (1984) established a Dk/t criterion of 87 Barrer/cm to avoid excess oedema during overnight wear. There were attempts in the interim to install alternate values, but there seems to be limited scientific basis to this rewriting of history. Fig. 24.14 gives a graphical demonstration of the

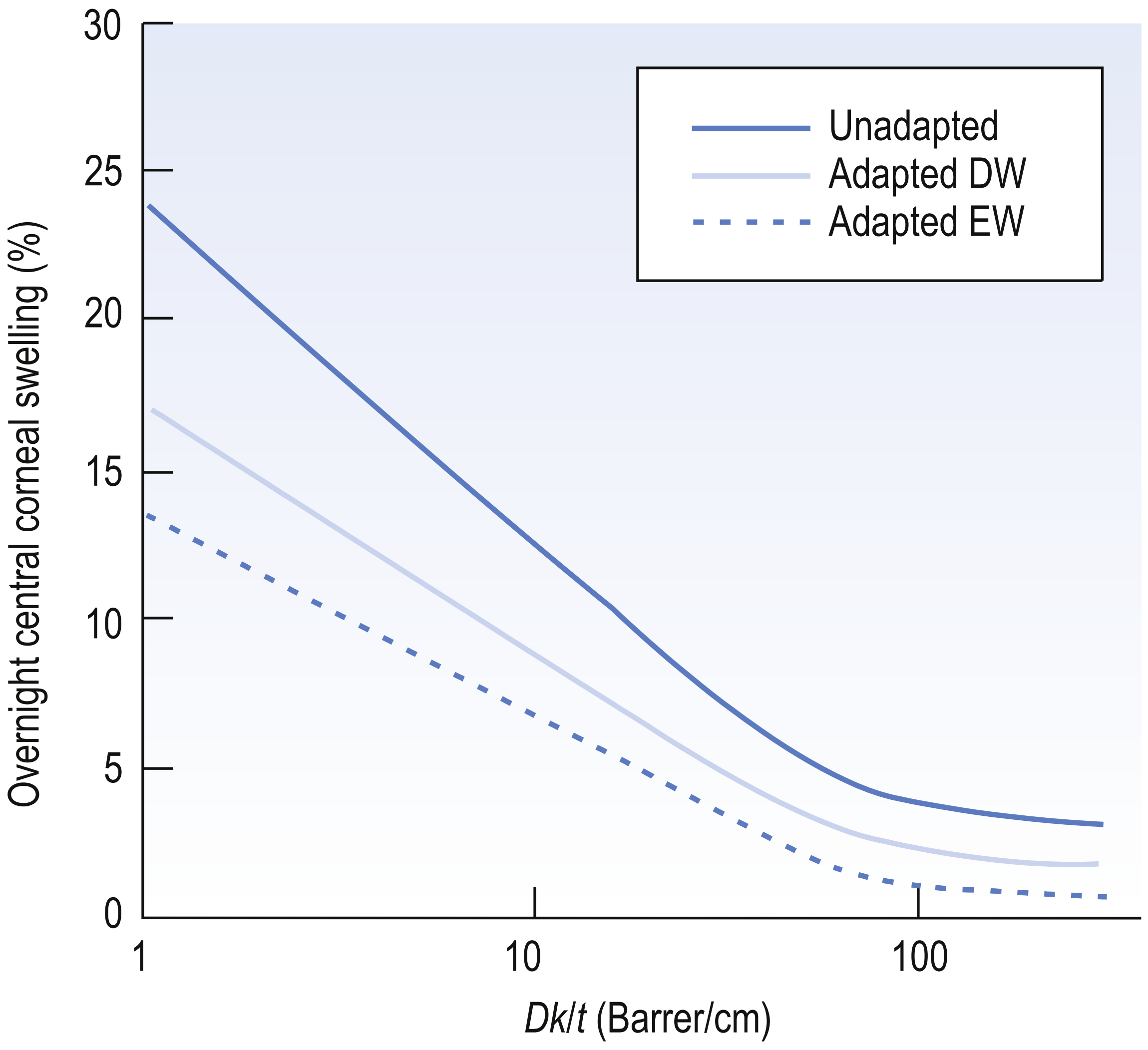

Fig. 24.13 Variation in overnight corneal swelling with wear of lenses of various Dk/t values for different levels of adaptation to daily lens wear (DW) and extended lens wear (EW).

variation in Dk/t for different lens materials manufactured at minimum practical thickness for various powers.

It is clear that hydrogel materials fall considerably short of the Holden–Mertz criterion. Most SiHy and some rigid lenses meet the desired level. However, the use of Dk/t values as a concept falls short of providing a simple index by which the negative impact of a lens can be assessed. For example, doubling the Dk/t does not double the amount of oxygen available.

Consumption values provide a more meaningful index of the corneal oxygen supply as these are direct linear estimates of the volume of oxygen metabolized and of the energy thereby delivered (Brennan, 2005). Fig. 24.15 plots a mathematically derived relationship between consumption and the anterior corneal oxygen tension.

Comparison with Dk/t values and known swelling at these values enables further estimates of corneal swelling for various closed-eye oxygen tensions. This information is illustrated in Fig. 24.16. Table 24.2 presents data for consumption values for various lens types under closed-eye conditions. It is evident that there are decreasing returns in overall consumption for increasing values of Dk/t.

Although corneal oedema is the most-studied short-term response to closed-eye contact lens wear, two other acute effects are worthy of note – limbal hyperaemia and endothelial blebs. The extent of both limbal hyperaemia (Papas et al., 1997) and endothelial blebs (Inagaki et al., 2003; Brennan et al., 2008) has been associated with oxygenation, and both conditions are reduced when lenses of high Dk/t are worn. Acute limbal hyperaemia (Fig. 24.17) may be important as a sign of corneal inflammation and prolonged limbal hyperemia may have clinical consequences as a precursor to corneal vascularization; however, the endothelial bleb response seems to be clinically inconsequential.

CHRONIC PHYSIOLOGICAL CHANGES

Over the years, researchers have diligently assembled an inventory of structural and functional changes in the anterior eye as a result of long-term EW of contact lenses. Many of these findings might be considered as harmless changes of physiological interest rather than clinically relevant pathological effects. The former category includes phenomena that are characterized by:

- a non-inflammatory nature
- a lack of threat to vision
- an absence of significance, unknown significance or limited significance when detected at a low level.

Long-term physiological changes have minimal impact on the rate of patient discontinuation from EW. It should be noted that these changes are not necessarily restricted to EW, and many of them are equally prevalent in daily wear. However, the

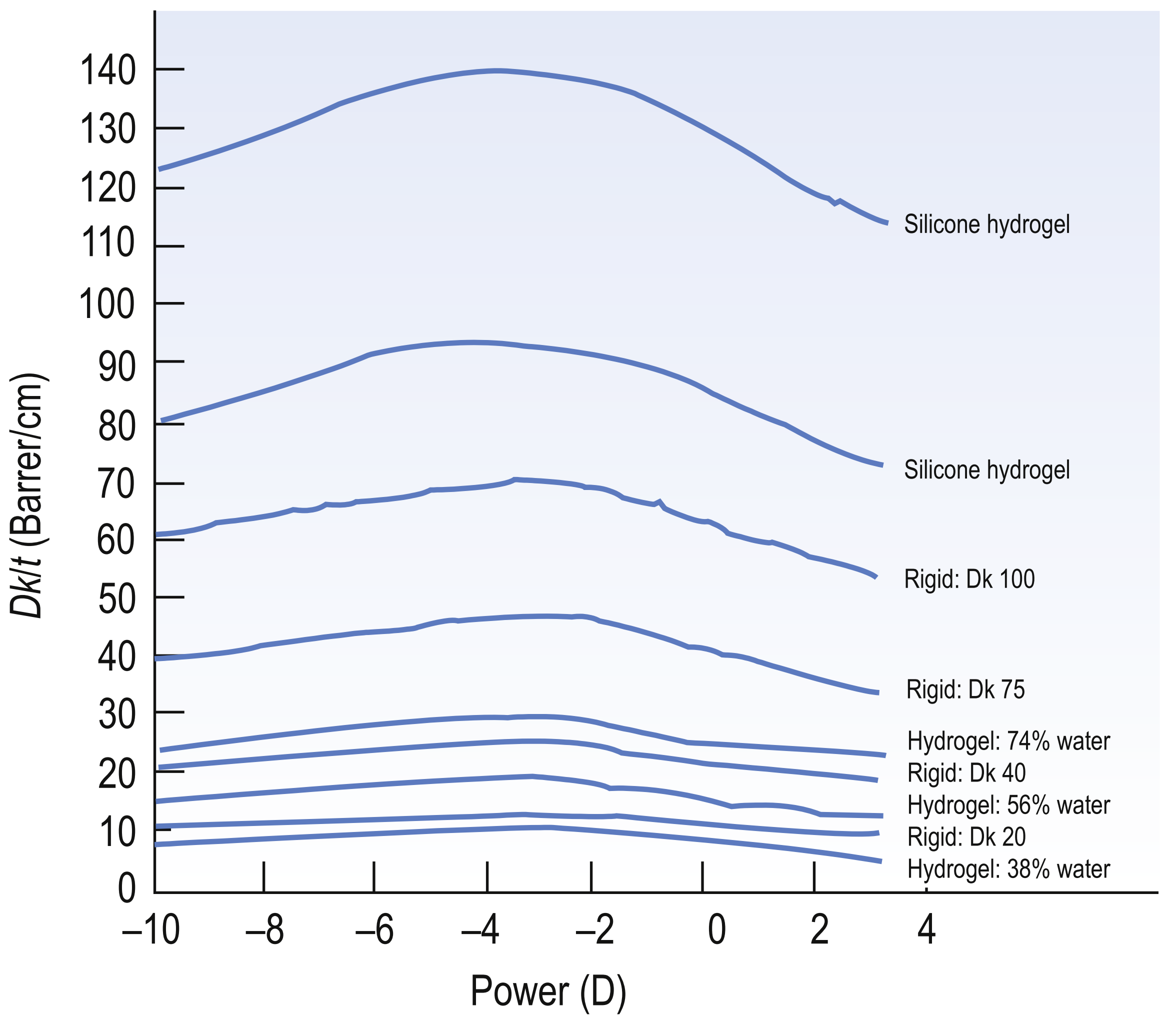

Fig. 24.14 Variation in Dk/t versus power for various lens types.

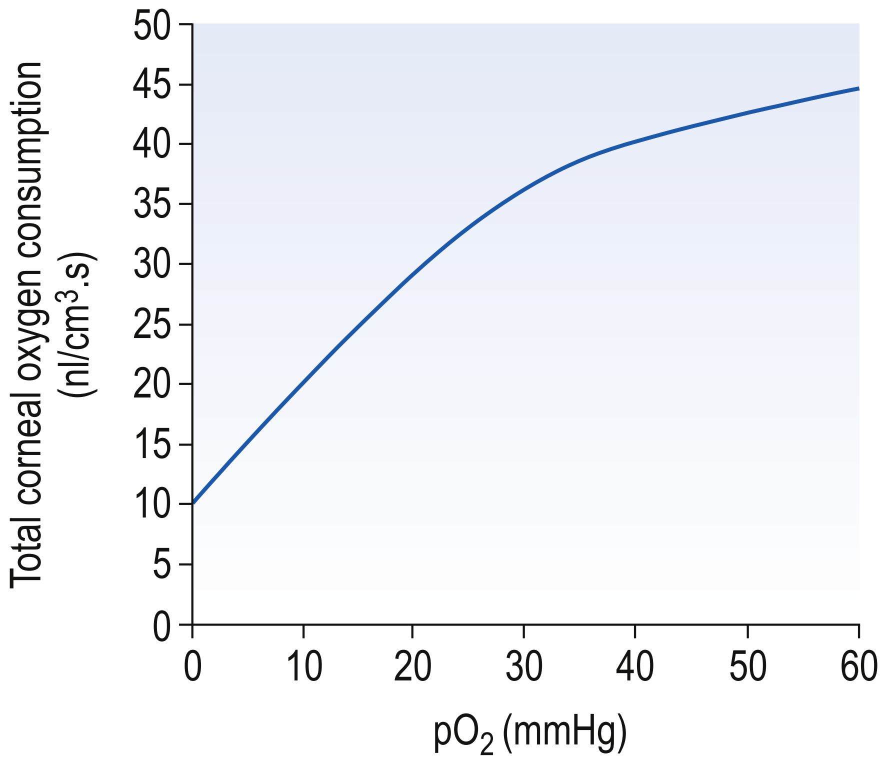

Fig. 24.15 Variation in corneal oxygen consumption versus anterior corneal oxygen tension.

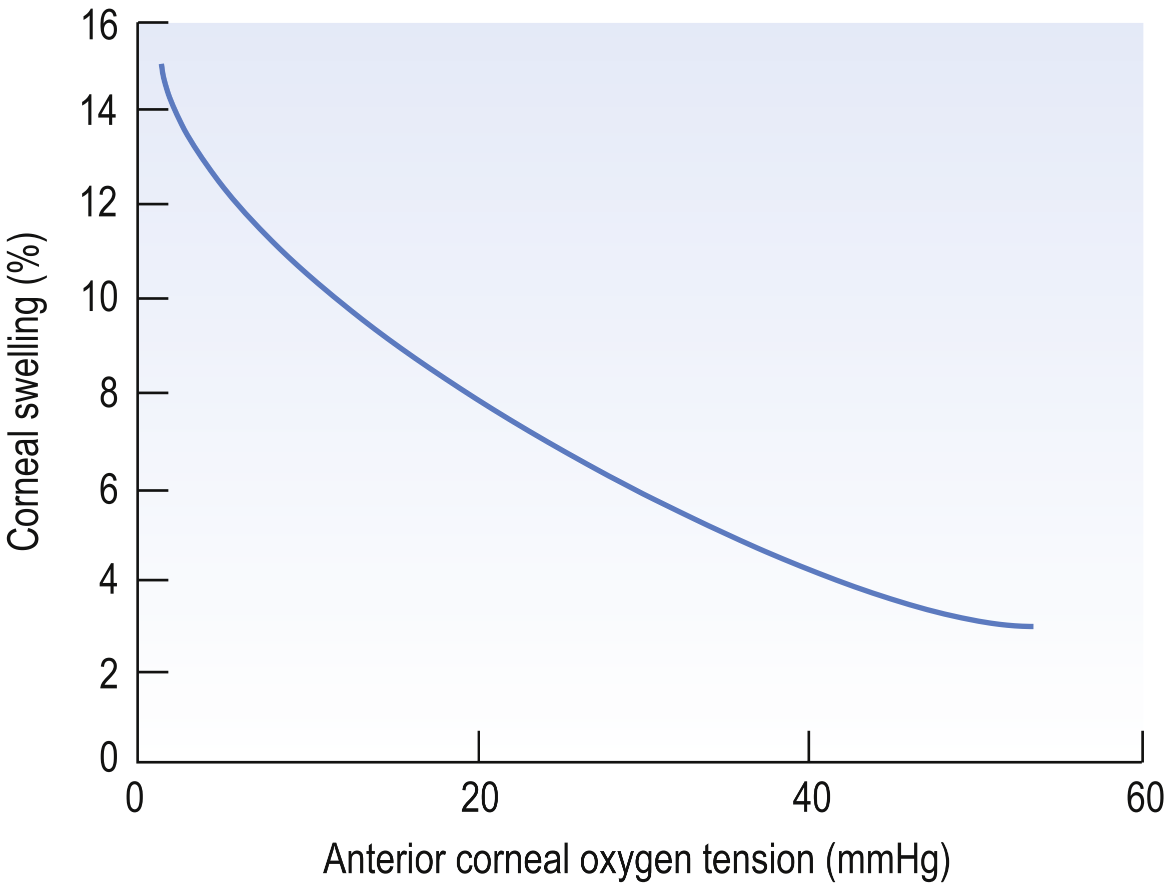

Fig. 24.16 Variation in overnight corneal swelling versus anterior corneal oxygen tension.

TABLE 24.2 Oxygen Consumption Estimates for Representative Lens Types Assuming Minimum Practical Thickness for −3.00 D Lenses during Closed-eye Wear

Lens Type	Oxygen Consumption $((nl/cm^3)/s)$
Low-water-content hydrogel lens	21
Medium-water-content hydrogel lens	30
High-water-content hydrogel lens	31
Rigid lens: Dk* 25	32
Rigid lens: Dk 50	40
Rigid lens: Dk 100	43
SiHy: Dk 110	44
SiHy: Dk 140	44
Silicone elastomer lens	45
No lens	45

*Barrer.

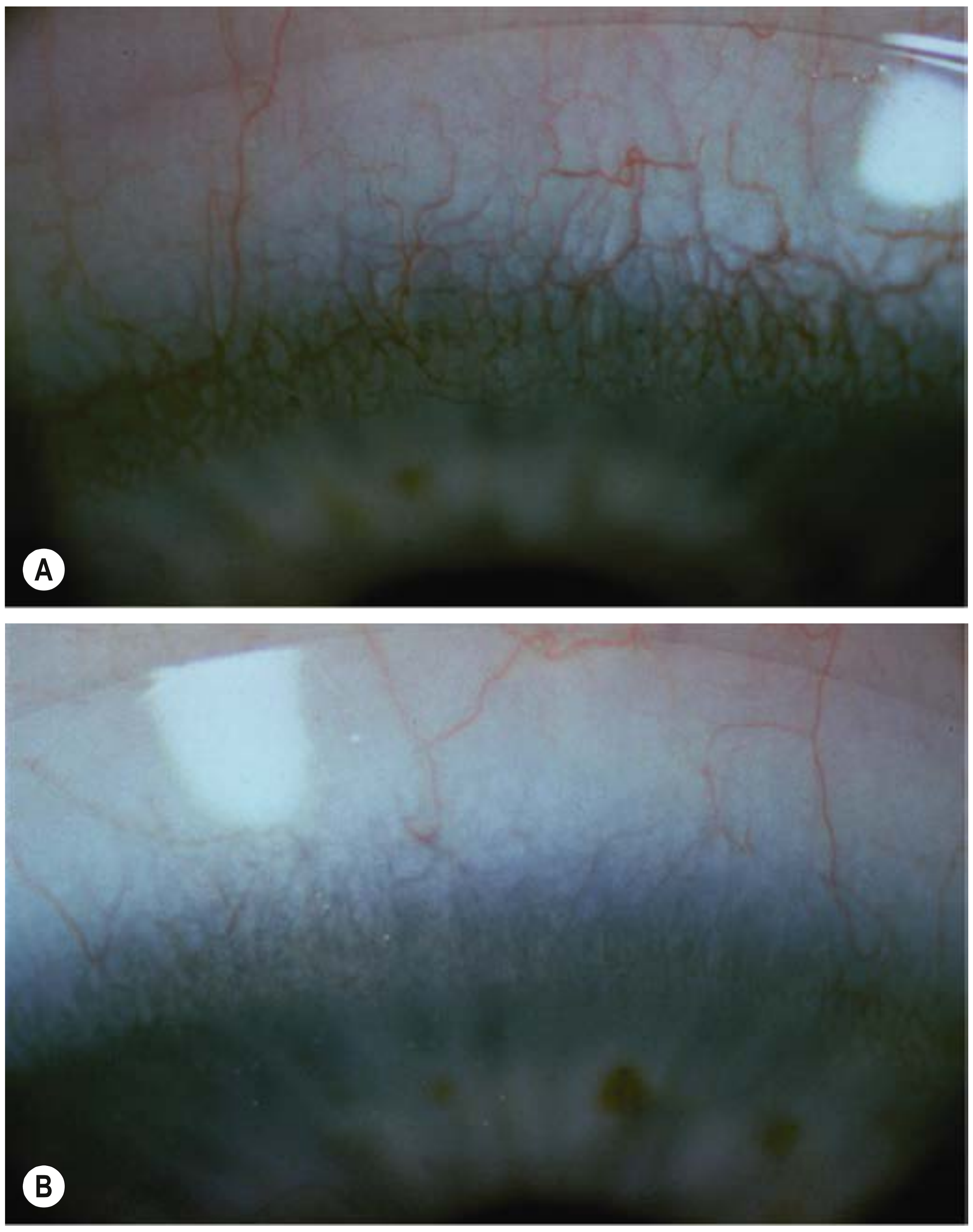

Fig. 24.17 Demonstration of the effect of hypoxia on limbal hyperaemia. (A) Grade 2.2 limbal hyperaemia is evident in this patient wearing a 38% water content hydroxyethyl methacrylate (HEMA) contact lens in one eye. (B) The same patient is wearing a high-Dk/t SiHy contact lens in the other eye; the extent of limbal hyperaemia (grade 1.0) is much less than that in the eye wearing the HEMA lens. (Courtesy of Eric Papas.)

presence of these changes may be indicative of a compromise to normal ocular function. It has been hypothesized that such compromise may leave the eye more susceptible to other pathology or to poor recovery following eye disease, but there is no evidence base to support such a proposition.

The following is a non-exhaustive list of changes that have been observed in humans during EW:

- altered epithelial oxygen consumption
- altered epithelial cell size
- altered epithelial cell sloughing rate
- altered epithelial permeability
- increased epithelial fragility
- epithelial thinning
- microcystic oedema (Fig. 24.18)
- excess corneal staining (Fig. 24.19)
- stromal thinning
- stromal neovascularization (Fig. 24.20)
- endothelial polymegethism (Fig. 24.21)
- altered corneal shape
- refractive changes
- reduced corneal sensitivity
- limbal injection
- eye redness.

There have also been studies that have documented alterations to the concentration of a wide range of aspects of tear composition, including cell types, protein levels and inflammatory components, and also altered ocular microbiota. Even corneal exhaustion – a syndrome characterized by lens intolerance, endothelial polymegethism and ongoing changes in corneal refraction and astigmatism – may be considered a severe physiological imbalance rather than a pathological state. Furthermore, animal studies have revealed changes in epithelial mitoses, adhesion, cellular junctional integrity, healing and cellular reserves of glycogen.

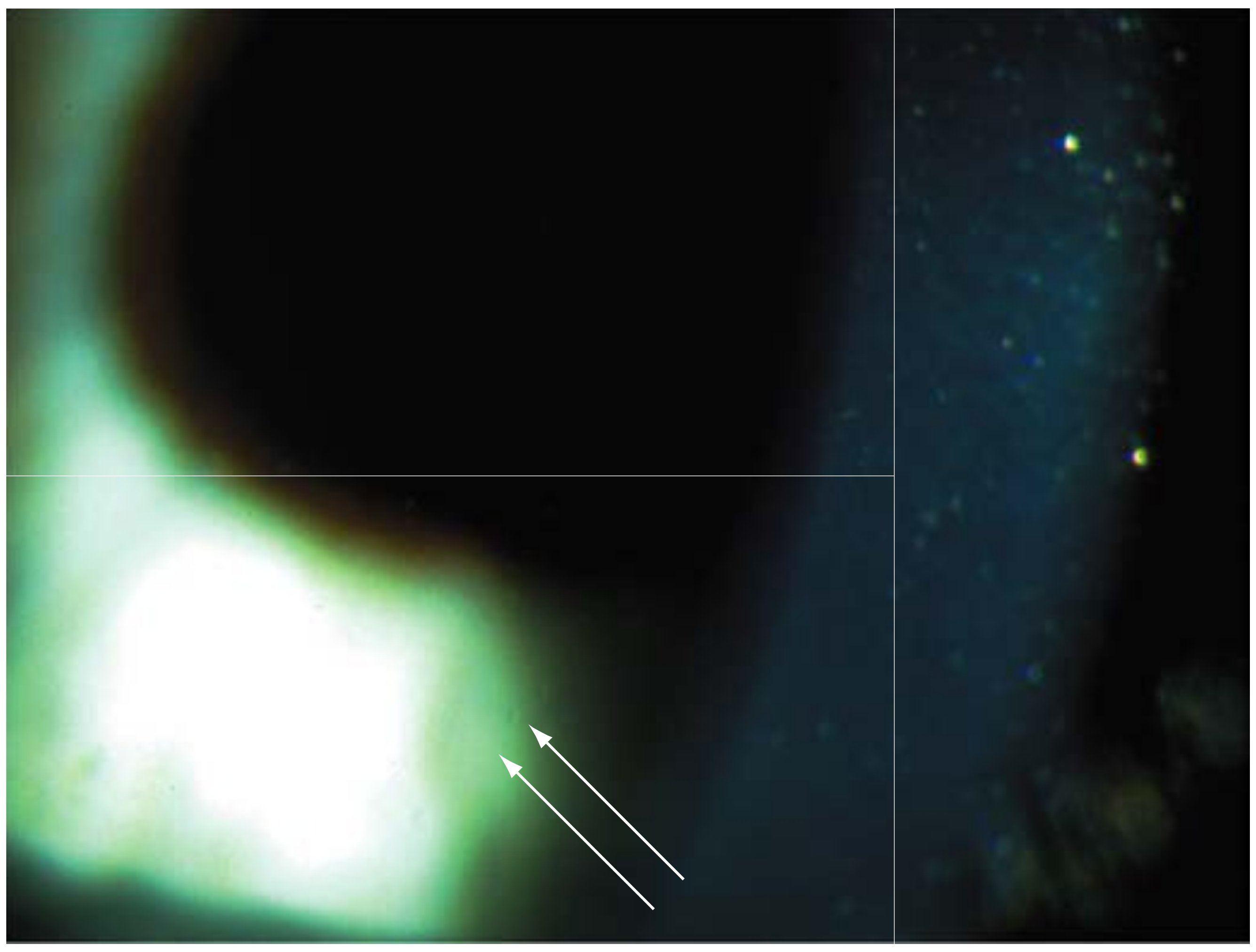

Fig. 24.18 Two microcysts (arrows) can be observed at the lower pupil margin, to the left of the optic section in which extensive tear debris is highlighted. (Courtesy of Ingebret Mojord.)

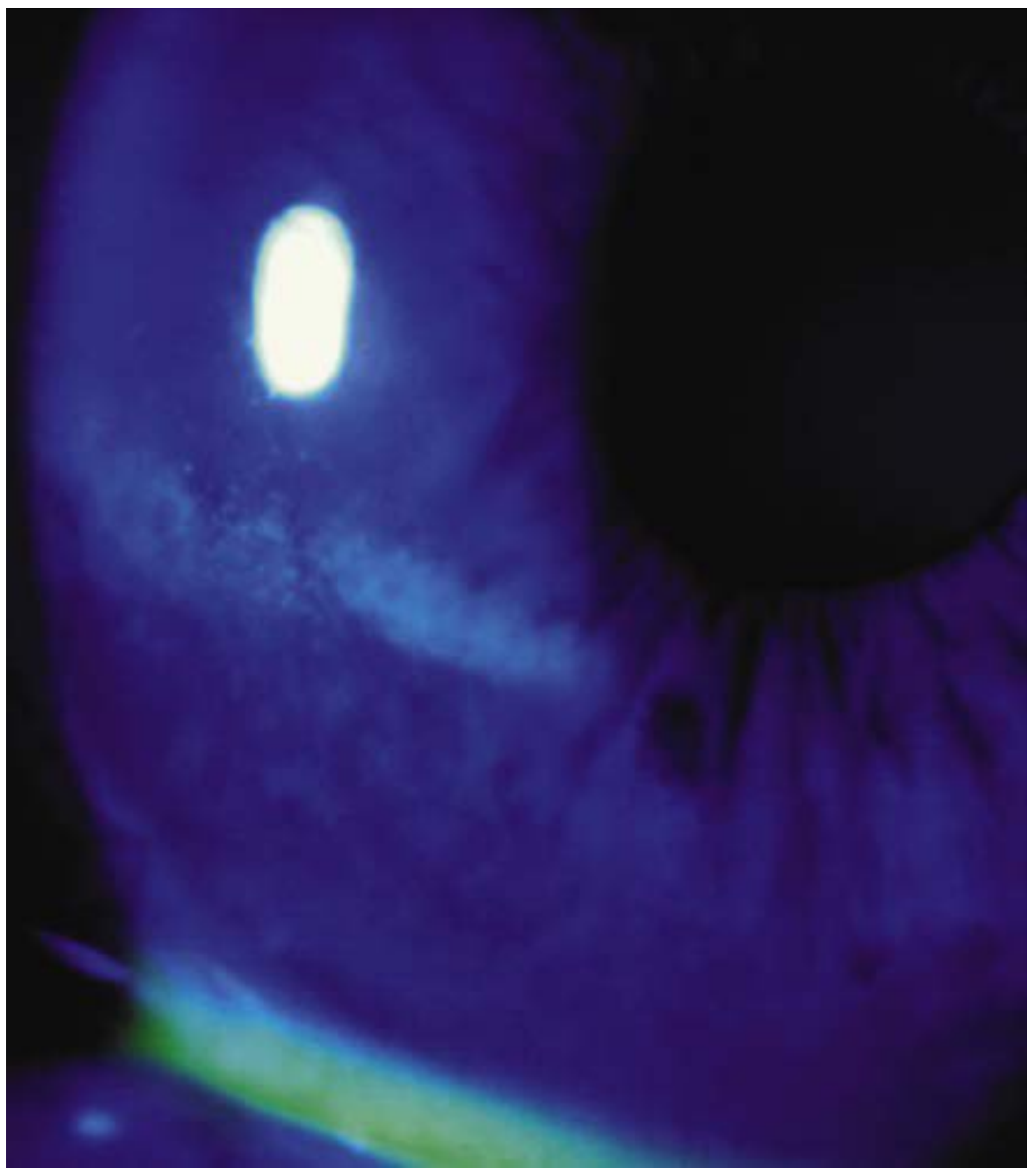

Fig. 24.19 Contact-lens-induced corneal staining. (Courtesy of Michael Hare.)

Hypoxia during closed-eye lens wear has been definitively linked to a great number of these corneal physiological changes. For example, the link between Dk/t and epithelial microcysts has been established in clinical trials. Evidence linking corneal neovascularization and endothelial polymegethism to chronic hypoxia is circumstantial but has widespread acceptance. Animal studies link hypoxia and low-Dk/t contact lenses with

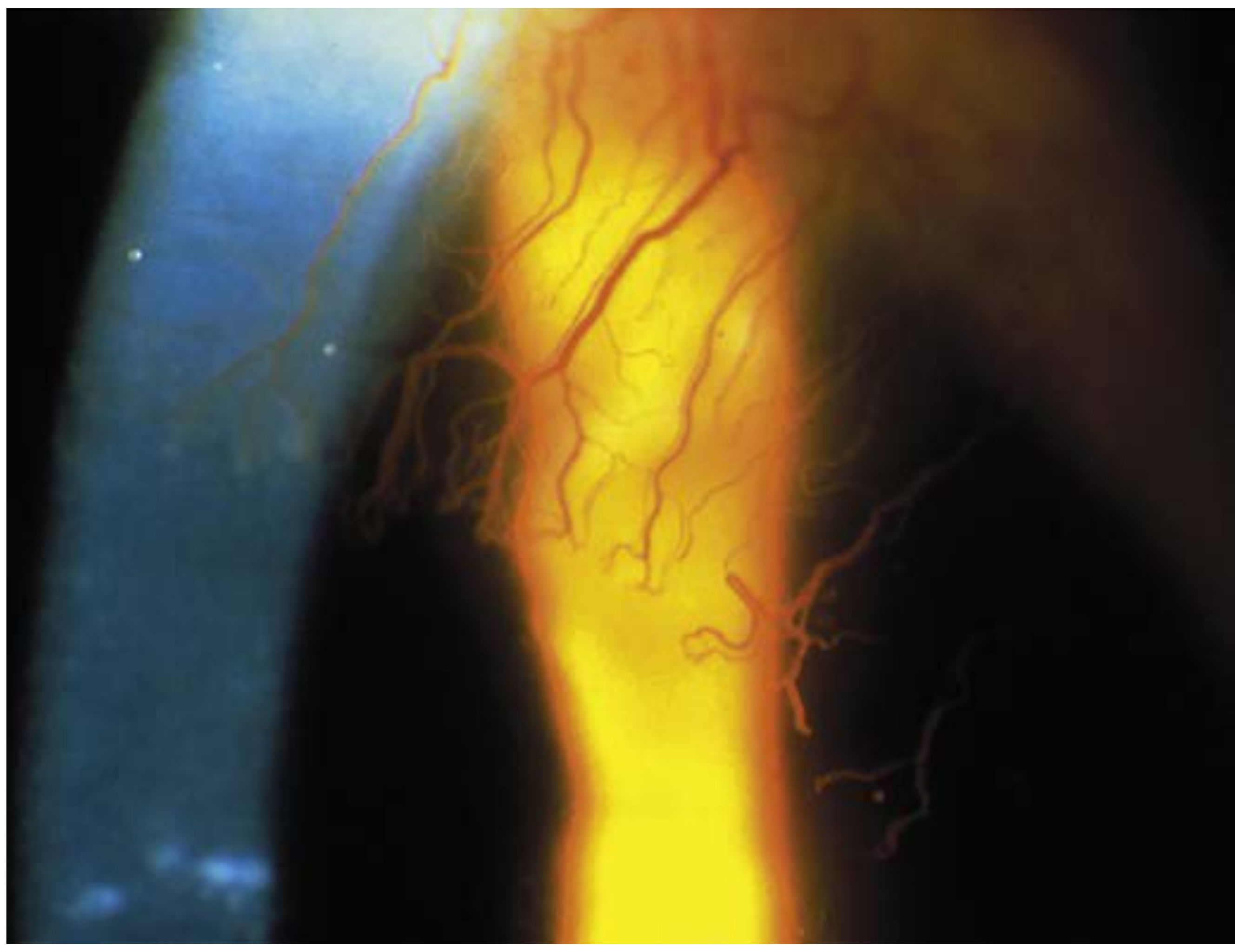

Fig. 24.20 Hypoxia during contact lens wear is implicated in causing vascularization of the peripheral cornea. (Courtesy of Patrick Caroline, Bausch & Lomb Slide Library.)

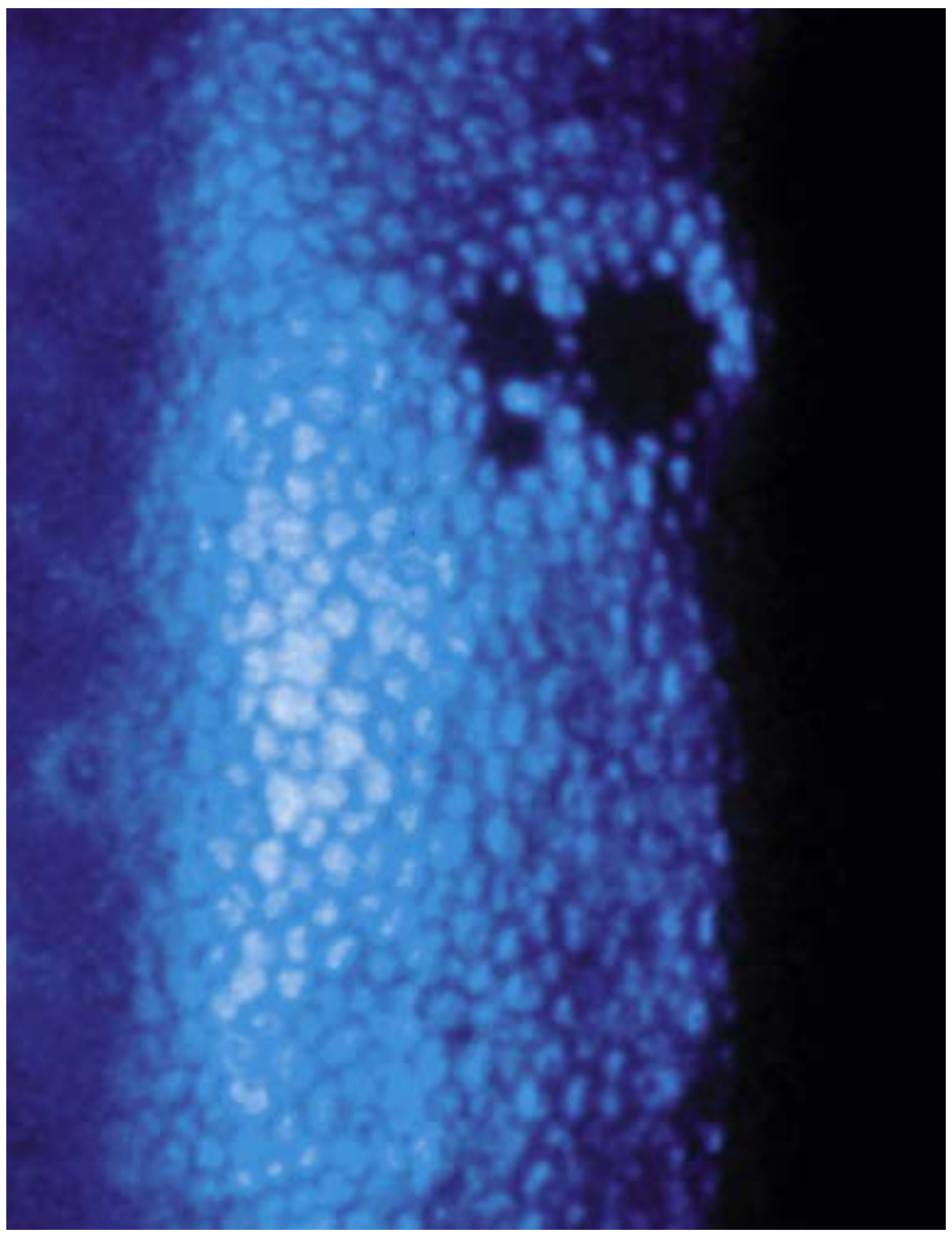

Fig. 24.21 Specular reflection of the endothelium following extended wear of a hydrogel lens, showing moderate polymegethism and general disruption as evidenced by the bright and dark patches. (Courtesy of Steve Zantos.)

slower epithelial healing following injury, bacterial binding to the intact cornea and episodes of corneal infection.

The main template for managing long-term physiological problems with contact lens wear was the landmark 'Gothenburg study' by Holden et al. (1985). These authors investigated the effects of 5 years of unilateral EW in a sample of 27 patients using the contralateral eyes as a control. The physiological markers under study included epithelial oxygen uptake, epithelial thickness, epithelial microcysts, acute stromal oedema, chronic stromal thinning, endothelial polymegethism, and limbal and bulbar conjunctival hyperaemia. The cornea of the lens-wearing eye showed a 15% reduction in oxygen flux, a 6% reduction in epithelial thickness, a 2.3% reduction in stromal thickness and a 22% increase in endothelial polymegethism. Epithelial metabolism recovered 1 month after ceasing lens wear, but the stromal and endothelial changes persisted for over 6 months. Patients with thinner corneas, higher endothelial cell densities and lower endothelial polymegethism before commencing lens wear showed fewer effects from contact lens wear. The study demonstrated that adverse physiological responses could be minimized by fitting lenses that were more regularly removed from the eye, more frequently replaced, more mobile on the eye and were more permeable to oxygen. To some extent, these objectives have been met by SiHy lenses. In particular, their high oxygen transmissibility has largely relegated major corneal physiological change during contact lens wear to the position of a historical curiosity.

A phenomenon known as 'myopic creep' has been attributed to chronic hypoxia during EW of hydrogel lenses. The changes are observed as differences in myopic progression rates between subjects wearing hydrogels compared with those using SiHy materials. However, the existence of such refractive changes should be considered against the following points: young contact-lens-wearing myopes are prone to modest increases in their refractive error; the design of the optics in refractive corrections can influence refractive development; corneal curvature and refractive index changes of the cornea during hypoxia are insufficient to explain the refractive shifts; and mechanical forces with thicker, stiffer SiHy lenses have been shown to be responsible for refractive effects (see below). Further research is needed to clarify the role of corneal physiology in refractive changes.

MECHANICAL EFFECTS

Rigid materials provide a range of positive effects when used for lens manufacture. These can include a stable front surface with accompanying optical benefits. The rigidity of the lens and the difference in shape between the posterior surface of the lens and the anterior cornea mean that a mismatch of shape occurs. This maintains a certain degree of tear pooling under the lens. With the blink there is a greater exchange of tears, which has the beneficial effect of flushing debris and bacteria away from the corneal surface and enhancing corneal oxygenation.

Notwithstanding the advantages described above, numerous problems arise with rigid lenses. Discomfort is influenced by the stiffness and size of a contact lens, and is the principal reason for discontinuation with rigid lenses. Larger, more flexible lenses, which provide less interaction between the lid and lens edge, provide greater comfort, at least initially. Lens rigidity and size also play an important role in complications such as 3 and 9 o'clock corneal staining. Air bubbles beneath the lens can be trapped against the cornea, producing an effect known as 'dimple veiling'. Pressure from the eyelid during sleep and settling of the lens can lead to close alignment of the posterior lens profile and the cornea, resulting in a depletion of the post-lens tear film and ultimately in lens binding, corneal distortion and lens edge imprint in the cornea.

Soft lenses contrast with rigid materials in that they drape across the cornea and thus show a high degree of conformity to corneal shape. This has the effect of minimizing post-lens tear film thickness. The thinness of the post-lens tear layer, along with the size of the lens and small amounts of lateral movement during the blink, limits the extent of tear exchange beneath soft lenses. During sleep, in particular, the lenses may become immobile, trapping a stagnant tear layer at the corneal surface.

It may take more than a few minutes following eye opening for lenses to recover mobility, although binding does not occur to the same extent as observed with rigid lenses. Lack of tear exchange means that sloughed cells, metabolic byproducts, trapped incidental tear debris and bacteria may be kept in contact with the corneal surface, presenting the opportunity for inflammatory and infectious conditions.

Direct pressure from soft lenses may play a role in the formation of some epithelial defects, which manifest as fluorescein staining. In particular, superior epithelial arcuate lesions (SEALs) may be induced by physical interaction of the lens surface with the superior region of the cornea (Fig. 24.22). There is some evidence that these lesions occur more commonly where lid pressure is greater, such as in Asian eyes, thereby increasing the physical effect of the lens. The mechanical properties of SiHy lenses have also directed attention to the issue of translucent post-lens debris, sometimes referred to as 'mucin balls' (Fig. 24.23). Although present with hydrogel materials, these phenomena occur frequently with SiHy lenses of higher modulus, especially when used in EW. The bodies appear to form as a result of shear forces related to lens stiffness and perhaps specific surface properties of the lenses. These appearances have not been specifically associated with an increase in adverse reactions and indeed one study links their presence to a decrease in the rate of CIEs (Szczotka-Flynn et al., 2011).

The greater stiffness of SiHy lenses has also led to refractive changes, a condition termed 'unwanted orthokeratology', especially with higher-modulus first-generation materials and in thicker, higher-powered lenses. Studies comparing SiHy lenses with hydrogel lenses during EW have noted differences in refractive progression between the two material types. Whereas 'myopic creep' with hydrogels has been attributed to physiological changes arising from hypoxia as noted above, corneal flattening in the SiHy-lens-wearing group may explain at least part of the difference in refractive changes between the lens types.

Lens surface friction and lens edge rubbing can lead to palpebral conjunctival changes, including lid-wiper epitheliopathy, hyperaemia and oedema. In association with possible antigenic effects of lens deposition, this can also lead to CLPC. More is presented on this condition below.

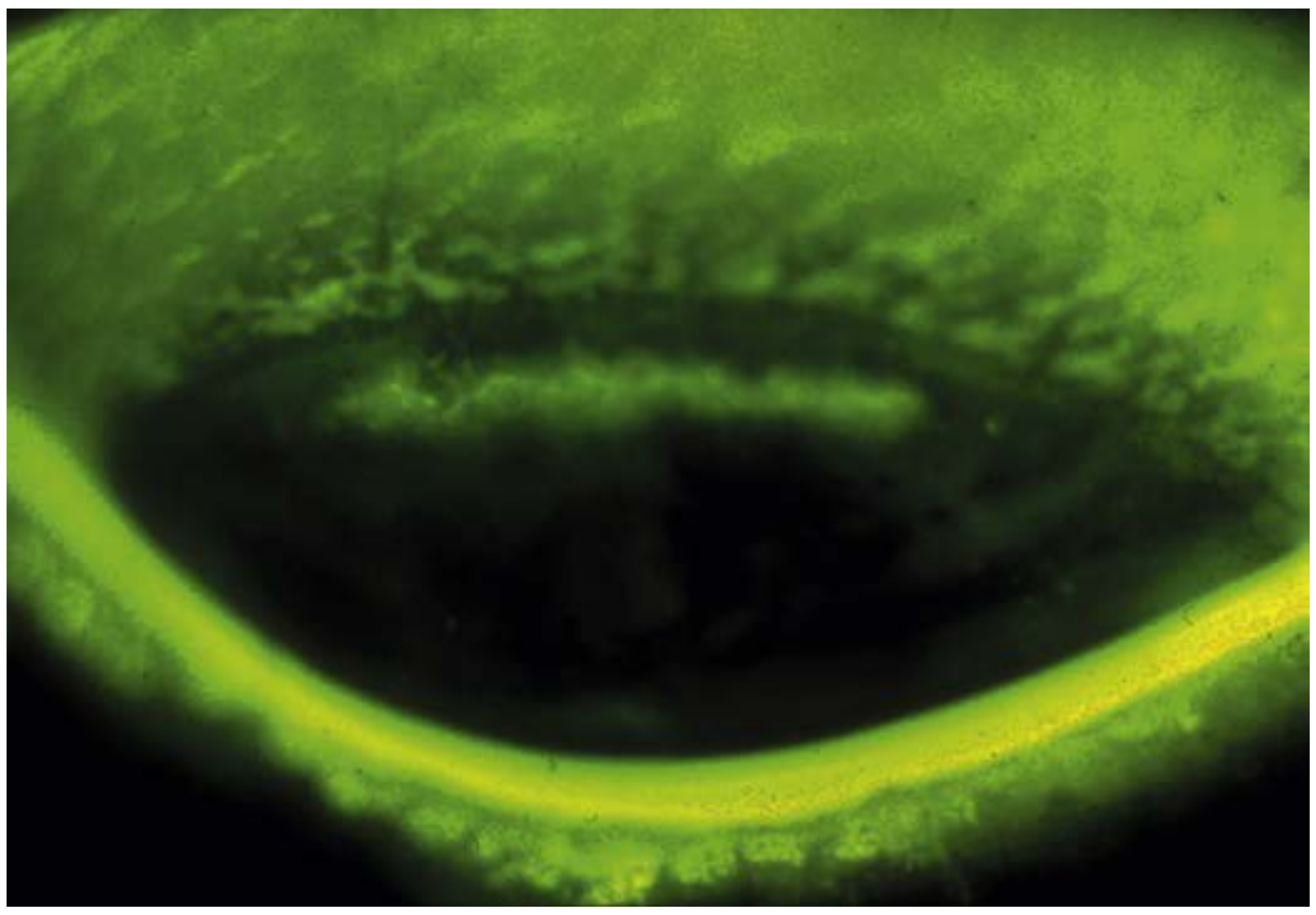

Fig. 24.22 Superior arcuate epithelial lesions may occur during wear of both hydrogel and SiHy contact lenses in extended wear. (Courtesy of Arthur Back, Bausch & Lomb Photo Library.)

Clinical Extended-wear Practice

IS EXTENDED WEAR SAFE?

Community and professional opinion determined that the rate and relative risk of microbial keratitis with EW as quoted above were unacceptable in 1989. Despite the publication of similar figures with SiHy lenses, EW of SiHy lenses continued to be pursued, albeit on a limited basis. Are there additional considerations that might have made a difference to prescribing rates with SiHy lenses?

There is a reasonable case for arguing that the concern over the rate of infection with hydrogel lens EW has been overstated and that the risk–benefit equation has not been adequately addressed (Brennan and Coles, 1997). Improvements in our understanding of the risk factors and prognostic symptoms and signs for infection quality and access to pharmaceutical therapies, treatment protocols and education of both practitioners and patients since the 1980s would appear to have resulted in fewer instances of very bad outcomes when microbial infection does occur. However, it is difficult to provide an evidence base for this apocryphal observation as comparable data across the decades has not been captured. Nonetheless, an infection rate

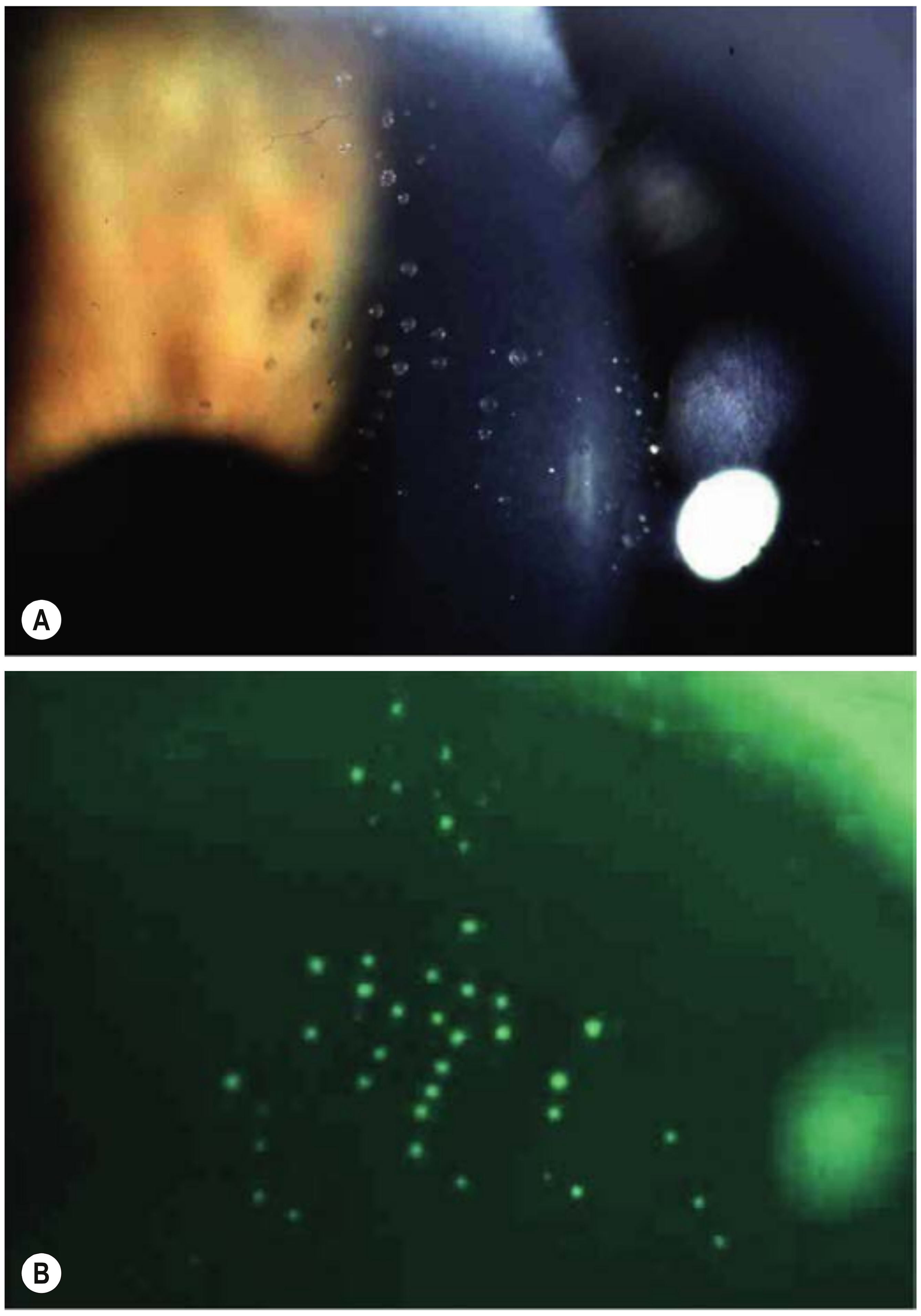

Fig. 24.23 Translucent spheroidal post-lens debris, referred to as 'mucin balls', is a common slit-lamp finding with silicone hydrogen lens wear. (A) Mucin balls observed behind the lens. (B) After lens removal, most of the mucin balls are washed away, but some remain. Fluorescein stains the remaining mucin balls, and fills epithelial indentations created by the mucin balls that were subsequently washed away. (Courtesy of Russell Lowe.)

with SiHy lenses that matches that with hydrogels may be reasonable considering the benefits that these lenses offer in terms of improving other aspects of ocular health (e.g. eliminating pathology relating to hypoxia) and patient convenience.

Studies investigating contact lens-related infection have used a clinical case definition, and commonly fewer than half of the cases yield positive cultures. Furthermore, those that yield a negative culture or were not cultured are known to be associated with less impact on visual outcome. Fig. 24.24 illustrates the culture status of ocular infections quoted in various publications and the proportion of these that can be attributed to vision loss with EW of contact lenses.

Vision loss with EW as a result of corneal infection is arguably the most critical measure of safety. Overnight contact lens use does produce a higher risk of vision loss than daily wear. Using a criterion of acuity of 6/12 or worse, approximately 28 to 40 per 100 000 patients in EW are likely to lose vision per year (Schein et al., 2005; Stapleton et al., 2008). On a comparable basis, refractive surgery is some 10 times more likely to lead to substantial vision loss over a decade (Fig. 24.25). Community concern of the danger of EW is difficult to reconcile with the public acceptance of procedures such as refractive surgery.

Another commonly used argument against EW is that the risk of suffering a microbial keratitis is higher than that with daily wear. However, daily wear is not a risk-free venture. The relative risk of corneal infection from daily wear of contact lenses is somewhere between 9 and 80 times that of members of western society without any predisposing factors (Dart et al., 1991; Qian et al., 2010). Sleeping in contact lenses adds a further risk, but only five times that of daily wear.

History has taught us some important techniques for avoiding detrimental outcomes with EW. One of the important factors identified by early epidemiological studies was the risk associated with longer periods of uninterrupted wear. Some experts advocated that decreased handling of lenses, by virtue of less-frequent lens removal, would minimize lens contamination and lead to fewer complications. However, the Contact Lens Institute study showed that the length of time between lens removals was related to the risk of microbial keratitis (Schein et al., 1989), a finding later confirmed by Dart et al. (1991). For this reason, in the 1990s the United States FDA issued a guideline recommending that the wearing time between lens removals during EW be restricted to less than 7 days.

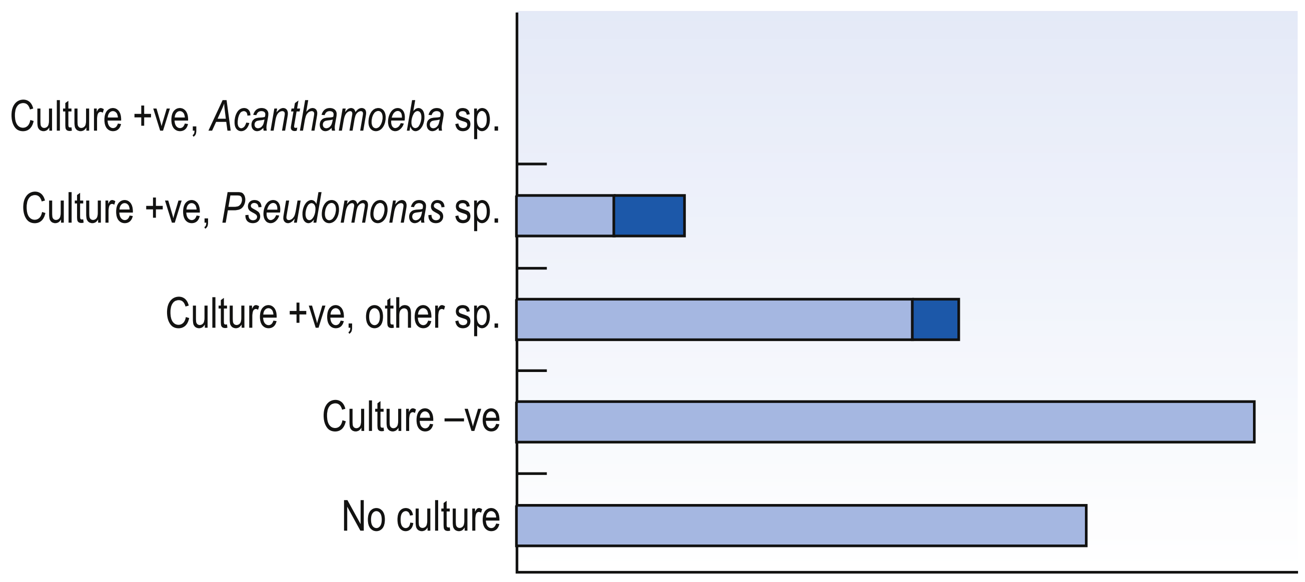

Fig. 24.24 Relative rates of different culture results to suspected corneal infections. The dark-blue section details those that are likely to cause substantial vision loss.

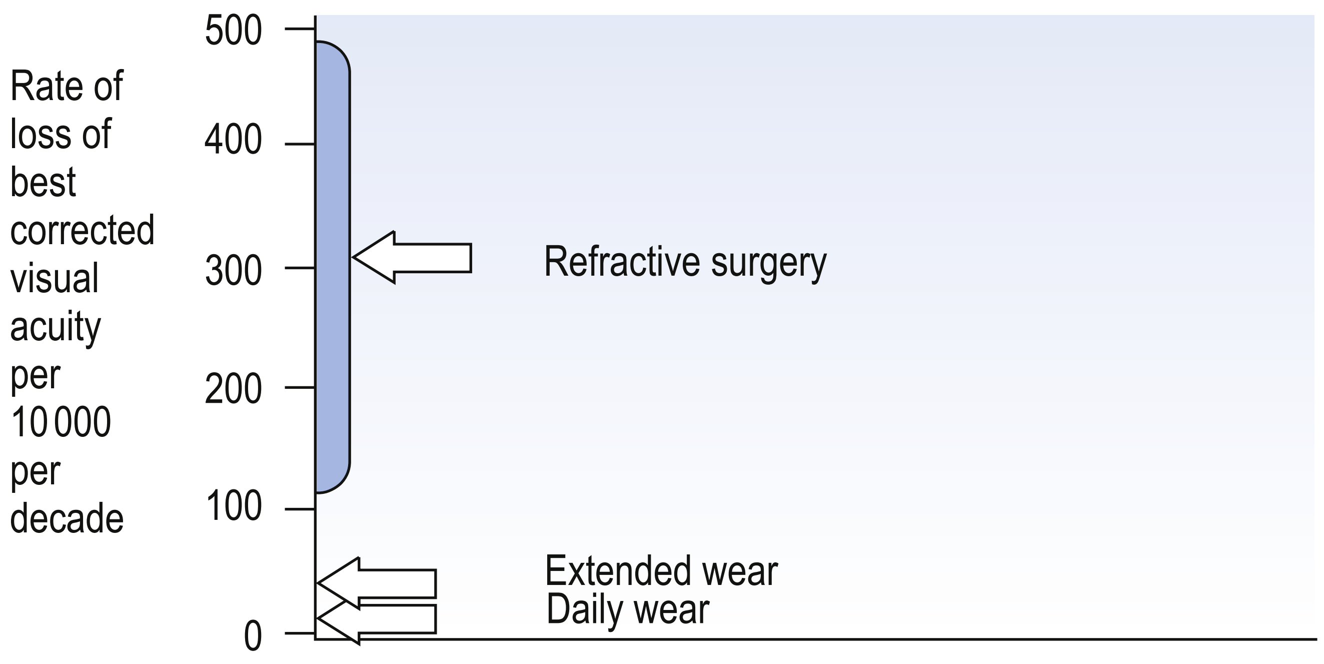

Fig. 24.25 Projected rate of substantial vision loss for various refractive options over a 10-year period.

With the expectation that high-Dk materials would lead to reduced microbial keratitis rates in EW, clearance was given by the US FDA for some SiHy lenses to be marketed for up to 30 consecutive nights of use. Two studies have been conducted in the SiHy era that address the issue in part as to whether longer periods of uninterrupted wear are as safe as shorter schedules. Schein et al. (2005) reported on a post-market surveillance study designed to estimate the incidence of microbial keratitis among wearers of a SiHy contact lens approved for 30-day continuous wear. They concluded that the rate of microbial keratitis with a wearing schedule of as many as 30 nights was similar to that previously reported for hydrogel lenses worn for fewer consecutive nights. However, they did not have a hydrogel lens control in their study and relied on an historical control as the basis for comparison. As the authors appropriately explained in detail, reported rates of microbial keratitis are very sensitive to study methodology and disease definitions (Efron and Morgan, 2006a) and numerous factors could influence the outcomes. The results should therefore be interpreted with considerable caution. In the second study, Stapleton et al. (2008) reported that longer periods of uninterrupted wear of all lens types (≥6 nights) did not present a statistically significantly greater risk for microbial keratitis than shorter periods. However, the odds ratio was 6.7, with 95% confidence intervals of 0.54 to 82.3. These figures do not provide support for the proposition of equivalence between longer and shorter wearing intervals and suggest that the study was not powered to make this distinction. Adopting the more conservative approach of restricting uninterrupted wear to 6 nights or less would appear to be more prudent from a safety perspective.

Patient safety is the primary concern when considering extended contact lens wear. There is no such thing as safe EW, so minimizing the risks of complications should be the principal concern of the practitioner. This is achieved by careful patient education, a conservative approach to care, accurate diagnosis of adverse events and the instigation of timely treatment where appropriate.

Application of Extended Wear in Practice

Incorporating EW into contact lens practice should be a proactive management decision. A number of systems should to be set in place, involving support staff, documentation and emergency precautions. In particular, the practitioner should provide the patient with a document disclosing fully the risks of EW, and informed consent should be obtained from the patient. Although it is not necessary to purchase additional equipment, practitioners should obtain grading scales to assess the severity of ocular complications of extended lens wear. Practitioners may also wish to adopt a scoring system for assessing the severity of CIEs (Aasuri et al., 2003).

The current standard for EW is to fit a highly permeable lens, most specifically a SiHy lens or, in certain circumstances, a rigid lens. Hydrogel materials may be safely used for EW, but most experts consider the induced hypoxia to be excessive when a broad range of high-Dk materials are available.

A most important component of EW practice is the diagnosis and management of adverse events. Below is a discussion on the significant adverse events that may be observed during EW, and a management plan for dealing with these problems.

MANAGING EXTENDED-WEAR COMPLICATIONS

Success in EW practice relies on a number of factors, the most important of which is diagnosing and managing adverse reactions. Details of the pathogenesis and risk factors are presented above. The following sections provide details of symptomatology, signs, differential diagnosis and a management plan. One of the encouraging features of this list is that the number of serious adverse events likely with EW is small.

MICROBIAL KERATITIS

Infectious ulcerative keratitis consists of invasion and colonization of the corneal epithelial and stromal tissue by a pathogenic microorganism. This problem is the only condition associated with EW that is an acute, serious threat to vision and the long-term health of the eye.

In the more severe cases, the patient is aware of rapidly developing irritation, which progresses to severe pain, both within the eye and around the periorbital region. Photophobia and reflex lacrimation are present, and aversion to light is often strong. On removal of the contact lens, the pain does not subside. The intensity of the pain leads the patient to seek assistance, possibly at a medical clinic or at an emergency room. On presentation, the patient will be in obvious distress. Ocular examination shows the ulcer as an epithelial defect with underlying stromal infiltrate. Small or large regions of the cornea may be involved, and the surrounding conjunctiva will be red and inflamed. There may be obvious mucopurulent discharge. As the disease progresses, the anterior chamber may become involved. Aqueous flare may be observed, and a hypopyon can form in very severe cases.

As discussed previously, in the early stages of the disease process, microbial keratitis can be confused with other non-infectious CIEs. Because of the potential for an adverse outcome, practitioners are advised to adopt the conservative approach of considering all such conditions as infectious until proven otherwise. In advanced stages, microbial keratitis is typically characterized by intense pain and photophobia that do not resolve with lens removal. The extent of pain is such that the patient frequently presents to the emergency room with a wet towel covering the eye. Other key features evident with a severe infection are the presence of epithelial defect, greater likelihood of discharge and corneal infiltrates. The presence of anterior-chamber reaction or mucopurulent discharge in association with these other signs should be treated as pathognomonic of an infectious corneal condition.

All eyes with suspected microbial keratitis should be cultured and receive immediate medical treatment. The patient may need to be hospitalized. The condition should be assumed to be a Gram-negative bacterial infection, and hourly application of antibiosis should be instigated. Nine out of 10 ulcers diagnosed as infectious resolve without serious loss of vision, but the key to this successful outcome is the speed with which treatment is instigated.

CORNEAL INFILTRATIVE EVENTS

There has recently been a significant shift in thinking in relation to the clinical evaluation of CIEs (Efron and Morgan, 2006b). In particular, there has been a shift away from the approach of classifying CIEs into various subtypes, such as the so-called contact-lens-associated acute red eye and contact lens peripheral ulcer (Sweeney et al., 2003). The new approach is to consider all CIEs as part of a disease continuum, and to make clinical decisions based upon an overall assessment of the severity of the condition (Efron and Morgan, 2006b). The reason for this shift in approach is that there is so much overlap in the clinical presentations of the various supposed subtypes of CIEs that clinical decision making based on such schemes is virtually impossible (Efron and Morgan, 2006c).

The simple reality is that, in the early stages of symptomatic CIE, it is not possible to tell whether the condition is indeed a non-infectious CIE or an early-stage microbial keratitis. The previous approach of attempting to classify a CIE as a contact-lens-associated acute red eye and contact lens peripheral ulcer was potentially dangerous, because the typical supposed clinical advice attached to such diagnoses was 'wait and see'. There are a number of recorded cases in the literature where this 'wait and see' approach was adopted, and the condition developed into a serious microbial keratitis (Sweeney et al., 2003). Thus, a non-infectious CIE is a condition that can be labelled as such only towards the end of the natural history of the disease process. From a clinical perspective, if a contact lens wearer presents with ocular discomfort and an infiltrative event is observed in the cornea, the condition must be considered to be a potential case of microbial keratitis, and managed accordingly.

PHYSIOLOGICAL STRESS

Corneal physiological stress may potentially be observed by both acute and chronic signs. There is widespread belief that the individual with chronic oedema is at risk of developing further complications and ultimately failure with EW. Certainly, an individual wearing a contact lens that provides a higher mean swelling in the population is more likely to suffer from hypoxic complications. Oedema assessment is difficult in practice without the aid of an optical pachymeter, an Orbscan instrument or an ultrasonic pachymeter, and few contact lens practices have ready access to such equipment. An alternative method of assessing the oedema level is by observing striae and endothelial folds. Fig. 24.26 plots the likely amount of overnight oedema present when striae are observed at a given time after awakening, based upon projections from known levels of striae with oedema, and studies examining the rate of corneal deswelling.

The likelihood of chronic physiological stress can be predicted from the short-term oedema response to lens wear. However, as mentioned above, it is sometimes difficult to make an assessment of the oedema by examination later in the day. Evaluation of the extent of limbal hyperaemia is another technique by which the oxygenation can be assessed, although this response is not specific to hypoxia.

One suitable method for assessing chronic hypoxia is to evaluate the epithelial microcyst response. It is important to note that microcysts are considerably smaller than vacuoles

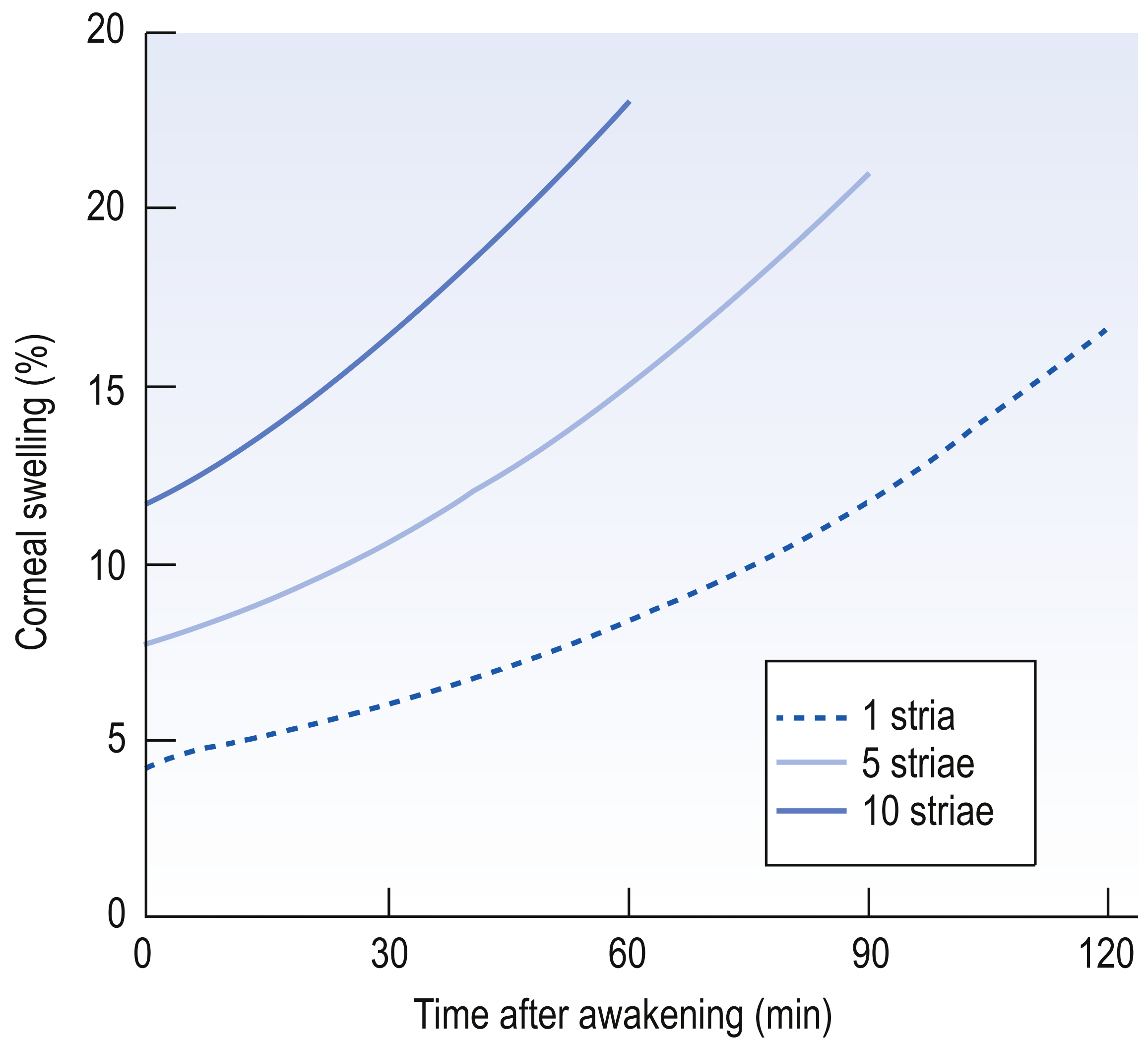

Fig. 24.26 Likely overnight oedema for a specific number of visible striae at a given time after eye opening.

and mucin balls, which are commonly confused with microcysts. Observation is best achieved by looking in marginal retroillumination with the focus at the level of the tear film such that small particles within the tears can be observed. During the blink, the small particles that do not move should be examined closely for reversed illumination. Once identified, the total number of microcysts in the cornea should be estimated. With a lens of adequate oxygen transmissibility, there should be no more than 10 microcysts present.

Another suitable method to assess long-term physiological compromise is endothelial evaluation. Chronic hypoxic stress is associated with altered endothelial regularity, and regular examination of the endothelium allows a practitioner to grade successfully different levels of anomaly (which must be related to patient age). Grade 2 endothelial irregularity in a patient under 30 years of age may be a precursor to further adverse corneal changes. Signs indicating the presence of chronic physiological stress should be managed by refitting with a SiHy lens.

VASCULARIZATION

Aside from microbial keratitis, corneal vascularization is the only pathological condition that may cause vision loss with contact lens wear. Vision is impacted only when the leading edge of the vascular bundle encroaches on the pupil. However, it rarely leads to vision loss as its development is slow and regular examination allows diagnosis and remediation. Vascularization is putatively caused by hypoxia and therefore is more common in hydrogel lens EW and with thick hydrogel lens use in daily wear. SiHy lenses virtually eliminate the development of vascularization. Where some vascularization has occurred with hydrogel lens wear, switching to SiHy lenses will see emptying of the vessels present in the corneal tissue and over a period of time there may even be retraction of such vessels.

PAPILLARY CONJUNCTIVITIS

This common contact lens complication involves invasion of the palpebral conjunctiva by inflammatory cells, including mast cells, eosinophils and basophils. It can occur with any type of lens wear, but will be more common in EW of hydrogel lenses and more common in first generation SiHy lenses.

The patient reports gradual onset of itchy eyes, awareness of excessive lens movement, lens deposition, lacrimation and possibly a stringy discharge. These signs will also be evident to the practitioner. On lid eversion, the most pronounced effect will be enlarged conjunctival papillae across the tarsal conjunctival plate.

Changing lens type, more-frequent lens replacement and a reduced interval between lens removals are useful ways to address CLPC. Early treatment of the condition with a mast cell stabilizer may enable the patient to continue with EW. If treatment is unsuccessful, reversion to daily wear may be necessary. Use of daily disposable lenses is another useful alternative. The condition will resolve over a period of weeks without any consequence to vision.

SUPERIOR EPITHELIAL ARCUATE LESIONS

Superior epithelial arcuate lesions (SEALs) present as regions of corneal epithelial abrasion that, as the name suggests, are located in the superior region of the cornea under the top lid. The stain is regularly punctate, but may coalesce and take on an arcuate shape, parallel to the limbus. The borders of the region of staining may be slightly raised. Occasionally there may be a diffuse infiltrate underlying the lesion. The condition may be more prevalent in Asian eyes.

Patients may be unaware of the problem and sometimes present with the condition at a routine follow-up examination. Others may report discomfort consisting of lens awareness and foreign-body sensation. The condition is self-limiting and will subside following lens removal. It is inadvisable to allow a patient with SEALs to continue with EW using the offending lens type. Refitting with a lens of different geometry or lower modulus will often solve the problem. Discontinuing EW is recommended if a change of lens type fails to resolve the inflammation.

Conclusion

Although extended contact lens wear remains attractive to the population, ongoing concerns about microbial keratitis mean this modality should be approached with due restraint. Practitioners contemplating an EW practice should carefully plan their management of lens wearers with this risk in mind. Silicone-containing hydrogel contact lenses should preferentially be used for EW because of their high Dk/t and associated benefits for corneal health.

Access the complete references list online at http://www.expertconsult.com.

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25

Sport

NATHAN EFRON

Introduction

A significant proportion of the population participates in sport or physical recreational activities (Australian Bureau of Statistics, 2016) (Table 25.1). Sport and recreation are often cited as the reason for seeking contact lenses. Daily disposable and reusable lenses are available in hydrogel and silicone hydrogel materials, in a wide range of parameters that will correct almost all potential wearers.

With modern contact lens technology, there is no reason why an ametropic sportsperson cannot compete with a normally sighted opponent on an equal basis from the standpoint of visual function. This chapter presents an overview of factors that should be considered when prescribing contact lenses for those participating in various sports. Although the emphasis is on competitive sports, the principles outlined are applicable to all forms of sport and recreational activity.

Deciding on the Best Form of Correction

The primary vision correction options are: soft contact lenses, rigid contact lenses, orthokeratology, refractive surgery or spectacles. Rigid lenses can be made in corneal, corneoscleral, miniscleral or scleral designs. Scleral lenses are usually prescribed only in very demanding circumstances; they will therefore not be considered in detail in this section (see Chapter 21).

REFRACTIVE SURGERY

Refractive surgery represents the most radical alternative. The benefits are that no correction needs to be worn for sport, and problems of lens loss, lens movement and lens maintenance are obviated. Although it might seem to be a perfect solution, laser correction is not without potential drawbacks. Corneal haze and regression can lead to less than perfect visual acuity, especially during the first few months following surgery. There is also potential for flap damage in patients who have had laser in situ keratomileusis (LASIK). Tetz et al. (2007) reported on a case where the left eye of a 39-year-old man was struck by the finger of a friend while the two were practising karate, resulting in loss of the flap, which occurred 3 years and 5 months after LASIK. Booth and Koch (2003) noted that a 38-year-old man sustained a dislocated flap after being struck in the left eye with a football more than 30 months after uneventful LASIK. These cases illustrate the need for LASIK patients to wear protective eyewear when participating in contact sports.

A comparison of the key features of the primary options for vision correction for sport is presented in Table 25.2.

Do Contact Lenses Enhance Sporting Performance?

Some clinicians have offered the anecdotal opinion that, compared with spectacles, contact lenses enhance the visual skills of the ametropic sportsperson; however, properly controlled clinical trials do not support these claims. Schnider et al. (1993) applied a battery of tests (including measurement of high- and low-contrast visual acuity, assessment of lens fit and subjective assessment of visual performance) to ametropic athletes wearing their spectacle correction versus low-water-content soft contact lenses. The authors found that, although contact lenses did not offer a measurable advantage over spectacles in terms of visual performance under these testing conditions, the psychological advantages were significant, and in this way contact lenses may enhance overall sports-oriented visual performance.

There have been suggestions that specially tinted contact lenses can enhance sporting performance. For example, Erickson et al. (2009) have demonstrated that the now-discontinued Maxsight Amber lenses (50% visible light transmission) and grey-green lenses (36% visible light transmission) provide better contrast discrimination in bright sunlight, better contrast discrimination when alternating between bright and shaded target conditions, better speed of visual recovery in bright sunlight and better overall visual performance in bright and shaded target conditions compared with clear lenses. However, the extent to which these visual performance attributes translate to enhanced sport performance is less clear (Porisch, 2007). The prescription of performance-enhancing tinted contact lenses for sport is discussed further in Chapter 22.

Environmental and Physical Constraints

The choice of contact lens for use in a given sport must be made with reference to the length of time that it takes to play the sport, the environment in which it is played and the general physical demands of the sport. The majority of sports are completed within 2 hours, which equates to a total period of lens wear of 4 hours, allowing for pre- and post-match activity during which lens insertion and removal would be impractical and/or undesirable. Even when these factors are understood, the lens of first choice may not be obvious. The most appropriate lens is sometimes determined only by trial and error.

ENVIRONMENTAL CONDITIONS

Contact lens wear is often associated with signs and symptoms of ocular dryness. These drying effects can be exacerbated by certain environmental factors, such as low humidity, wind and

TABLE 25.1 Participation by Males and Females in the 'Top Ten' Sport and Physical Recreation Activities in Australia (2009–2010)

Males		Females	
Sport / Recreation	Participation Rate (%)	Sport / Recreation	Participation Rate (%)
Walking for exercise	15.6	Walking for exercise	30.0
Aerobics / fitness / gym	11.2	Aerobics / fitness / gym	16.7
Cycling / BMXing	8.2	Swimming / diving	8.4
Jogging / running	7.5	Jogging / running	5.6
Golf	7.5	Cycling / BMXing	4.9
Swimming / diving	6.4	Netball	4.6
Tennis	4.4	Tennis	3.6
Soccer (outdoor)	3.7	Yoga	3.1
Cricket (outdoor)	2.8	Dancing	2.5
Australian rules football	2.6	Bush walking	2.3

*Percentage of the population over 15 years of age participating at least once during the past 12 months.

TABLE 25.2 Comparison of Different Forms of Vision Correction for Sport

Characteristic	Soft Lenses	Rigid Lenses	Orthokeratology	Spectacles	Refractive Surgery
Field of view	Full	Full	Full	Restricted	Full
Stability of vision (post-blink)	Excellent	Good	Excellent	Excellent	Excellent
Glare	None	In low light	None	None	Some post-surgery
Glare protection tint possible	Cosmetic only	No	No	Yes	N / A
Ultraviolet protection possible	Yes	Yes	No	Yes	N / A
Initial comfort	Good	Poor	Fair	Good	Fair
Long-term comfort	Good	Good	Excellent	Good	Excellent
Adaptation required	Very little	Yes	Yes	Sometimes	N / A
Suitability for intermittent use	Yes	Not usually	No	Yes	No
Disposability viable	Yes	No	N / A	No	N / A
Risk of loss	Low	Moderate	N / A	Low	N / A
Risk of dislodgement during wear	Low	Moderate	Nil	High	N / A
Risk of damage during wear	Low	Low	Nil	High	Moderate (LASIK flap mislocation)
Risk of damage with handling	High	Low	Low	Low	N / A
Ease of care	Simple (nil for daily disposable)	Simple	Simple	Simple	N / A
Initial cost	Low	Moderate	High	Moderate	High
Ongoing costs	High	Moderate	Moderate	Nil	Nil
Cost to correct astigmatism	High	Low	Only limited correction possible	Low	High
Bifocal correction possible	Compromise	Very difficult	No	Yes	Monovision
Use in rain	Good	Good	Excellent	Poor	Excellent
Susceptibility to fog up	No	No	No	Yes	No
Susceptibility to dirt up	No	No	No	Yes	No
Risk of complication	Low	Negligible	Low	None	Moderate

LASIK= laser in situ keratomileusis; N / A= not applicable.

visual tasks. Wearing silicone hydrogel contact lenses may provide greater relief of subjective ocular discomfort in adverse environmental conditions than that afforded by both the habitual lenses of contact lens wearers or no contact lens wear (Young et al., 2007; Ousler et al., 2008).

Sports are played in almost every environment. Climatic conditions play a role in disease severity and causative organism in contact-lens-related microbial keratitis and therefore have implications for practitioners involved in contact lens care of wearers who may be engaging in sporting activities in the tropics (Stapleton et al., 2007). The following environmental conditions are considered as they will directly affect the choice of lens for the sportsperson.

Cold

Many sports take place in cold environments, typically in close proximity to ice and snow. Because the intrinsic temperature of the eye and tear film is around 34°C (Efron et al., 1989), contact lenses cannot freeze up in the eye. In an extensive survey of 105 contact lens wearers who were frequently engaged in cold-weather sports, Socks (1983) found no evidence of eye injury or disease. 'Eye redness' was the most common complaint of rigid lens wearers; soft lens wearers most frequently complained of slightly reduced vision. Large-diameter, medium-water-content hydrogel, or silicone hydrogel soft lenses may provide the best results in cold conditions.

Altitude

The ability of oxygen to reach the cornea through a contact lens, which is a key prerequisite to sustain good ocular health during lens wear, is a function of the oxygen transmissibility of the contact lens and the partial pressure of oxygen in the atmosphere. This argument is particularly relevant to sports that are played at altitude. The partial pressure of oxygen in the atmosphere decreases with altitude, which effectively means that the tolerance of the eye to a lens of given oxygen performance will decrease with increasing altitude. In addition, temperature falls about 10°C per 1500 metres increase in altitude to a minimum of −50°C; the effects of extreme cold on the cornea were dealt with in the previous section. There appears to be a significant connection between the level of available oxygen during contact lens wear and improved patient symptoms of comfort, including dryness (Dillehay, 2007). In view of the rarified oxygen atmosphere at high altitude, and the length of time lenses may be worn, high-oxygen-performance silicone hydrogel lenses are indicated.

Bauer (2015) surveyed the experience of 158 contact lens wearers while trekking at high altitude in Nepal. The majority of the participants (78%) reported no problems with their lenses (daily disposables, soft lenses, extended-wear lenses, hard / rigid lenses) during their stay, although dry air, dust, wind, cold temperatures and difficult hygiene maintenance were challenging. Freezing lenses and freezing solutions were additional challenges. Almost 60% of participants had not sought any pretravel health advice, and 22% of trekkers experienced a variety of problems. Bauer (2015) concluded that remote and wilderness areas provide a challenge for appropriate contact lens wear and care. Based on the findings of his survey, Bauer (2015) made the following recommendations:

- Lodges should provide better access to clean water, mirrors and lighting.
- The decision between the potential risk of infection due to touching lenses (daily disposables, soft / hard lenses) and the potential risk of corneal erosion (extended-wear lenses) needs to be made in pretravel consultations.
- Travel health professionals and travel agencies should remind contact-lens-wearing trekkers to assess carefully their wear and care routine so as to accommodate potentially challenging conditions.

Dirt and Dust

Rigid contact lenses are prone to trap debris beneath the lens and are clearly contraindicated in dirty and dusty environments. Also, dirty and dusty sporting environments are typically associated with intense physical activity and a greater risk of dislodging the lens, which are further factors contraindicating the use of rigid lenses. Large-diameter soft lenses are the lens of first choice in such environments. Lens water content and oxygen transmissibility are less critical factors. Orthokeratology has a distinct advantage in such environments, in that the lenses are not present in the eyes to trap dirt or dust, or to become dislodged.

Aquatic Environments

Aquatic sports are defined here as those that take place immediately above or in water, but generally not deeper than 2 metres. Edmunds (1992) has suggested that sportspersons engaged in aquatic activities be advised of the following strategies for avoiding lens loss and preserving eye health:

- Close eyes on impact with water.
- Do not open eyes fully when under water; instead, squint and maintain a head position in the direction of gaze.
- Upon surfacing, gently wipe water from closed lids before opening eyes.
- Irrigate eyes with fresh saline upon leaving the water.
- Remove and disinfect lenses shortly thereafter.

Contact lens wear is known to increase the risk of infection slightly, and the use of lenses in aquatic environments must be considered as an additional risk factor. Choo et al. (2005) found that wearing a hydrophilic lens while swimming in a chlorinated pool allows accumulation of microbial organisms on or in the lens, in both hydrogel and silicone hydrogel materials. Wu et al. (2011) reported that the wearing of goggles over contact lenses reduced the number of bacterial colonies found on the lens surface. However, infections are rare, and the risk of lens-related eye disease can be reduced to almost zero if lenses are removed, cleaned and disinfected in the prescribed manner soon after leaving the water. Ideally daily disposable lenses can be worn and then discarded.

Larger lenses provide the greatest on-eye stability, which is of particular benefit when engaged in dynamic water sports (Banks and Edwards, 1987). Goggles worn over contact lenses, in the same way as worn by a non-lens wearer, will ensure good vision, help preserve ocular health and help reduce lens loss.

Komori et al. (2013) reported that, over the previous 20 years, Japanese water polo players were increasingly using contact lenses for this sport, presumably as a result of the increasing availability and affordability of disposable lenses. In 2011, 86% of Japanese water polo players wore contact lenses during games, and 96% wore soft lenses.

A survey of coaches involved in a number of different sports found that swimming was the sport associated with the lowest level of recommendation for contact lenses, although this trend was reversed with appropriate education (Zeri et al., 2011).

Subaquatic Environments

Various authors advocate the use of both rigid lenses (Holland, 1993) and soft lenses (Bennett, 1985) for scuba diving. All seem to agree that the use of contact lenses with a standard facemask is preferred to the use of prescription facemasks. As a result of the increased physical pressure experienced during deep dives, inert atmospheric gases, in particular nitrogen, dissolve in body tissues. As the diver returns to the surface slowly, these gases are released and become trapped as minute bubbles beneath the lens (Holland, 1993). This problem is especially acute with rigid lenses because of the extremely low permeability of rigid lens materials to nitrogen; the nitrogen gas cannot escape by permeating through the lens (Fig 25.1). This phenomenon can be alleviated by fitting lenses of very high gas permeability, such as silicone hydrogel lenses, and encouraging the diver to concentrate on blinking. Brown and Siegel (1997) concluded there are no compelling reasons to change lens types in patients who are already fully adapted lens wearers. Nevertheless, silicone hydrogel lenses are the modality of choice.

Ultraviolet Light

Sporting activities conducted on water, sand or snow will result in the sportsperson being exposed to excessive ultraviolet (UV) radiation, which can cause skin sunburn and solar keratitis in the short term, and cataracts (Taylor et al., 1988) and pterygia (Hill and Maske, 1989) in the long term. Thus, contact lenses with UV protection tints are indicated (Cullen et al., 1989). It must be recognized, however, that such lenses will not prevent excessive and potentially damaging UV light from reaching those parts of the external eye that are not covered by the lens, such as exposed parts of the cornea (in rigid lens wearers) and the bulbar conjunctiva. The use of goggles with UV-absorbing tints, to be worn over UV-absorbing contact lenses, constitutes

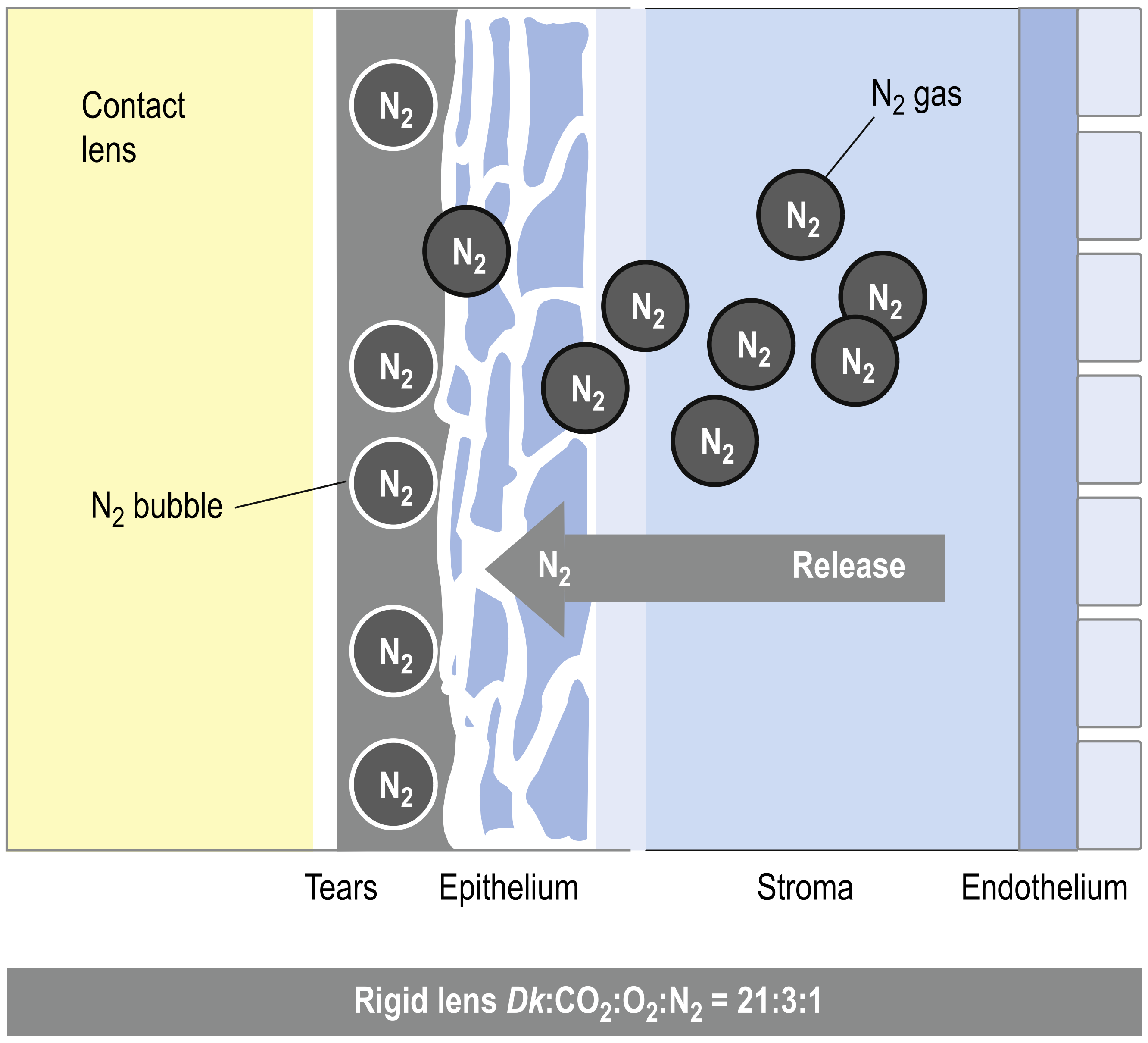

Fig. 25.1 Nitrogen gas (N_2) forms in the cornea during decompression but cannot vent through the lens owing to the relatively low nitrogen permeability of rigid lenses.

an extra precaution for periods when the mask is removed. Skiers should be reminded also to apply UV protection creams to the remaining exposed skin on the face and neck. In surfing, where use of goggles may not be appropriate, a UV-absorbing contact lens will at least afford some protection.

PHYSICAL CONDITIONS

Special consideration needs to be given to ametropic sportspersons to facilitate their full participation in sports characterized by extreme body movement, body contact, airflow and gravitational forces. Eye, head or even general body protection is often mandatory for the sportsperson subjected to such physical extremes.

Extreme Body Movements

Stability of a contact lens in the eye is essential for the sportsperson participating in activities that involve extreme body movements. Spectacles and sunglasses may be unsuitable or even banned in many of these sports. Rigid lenses are contraindicated in view of the high risk of dislodgement during the sports action. Large-diameter soft lenses provide the greatest stability when excessive eye, head and body movements are involved. The lens should centre well and display minimal movement. Slightly thicker lenses resist folding up in the eye.

Body Contact

The same considerations as above apply here, along with the additional factor of physical contact. Those participating in full-body contact sports can be subjected to excessive body shock and jarring, and there is also the possibility of direct physical insult to the face and eyes. The obvious extreme example is boxing; most authorities governing this sport (such as the British Boxing Board of Control) ban the use of contact lenses. The governing bodies of many body contact sports encourage the wearing of eye and face protection via the use of helmets and masks. In sports where this is optional, the contact-lens-wearing sportsperson is advised to wear such protection to preclude accidental dislodgement of the lens through direct physical contact to the eyes by an opponent. In such situations, large-diameter soft lenses offer greatest stability, and rigid lenses are contraindicated. Daily disposable lenses are preferred as it is possible to have many spare replacement lenses available in the event of lens loss.

Airflow

Significant airflow over the eyes typically occurs in the course of speed sports, such as luge or motor cycle racing. The most extreme conditions of airflow over the eyes are experienced by parachutists during free-fall, which can last up to 60 seconds. Airflow over the eyes can reach up to 290 km/h. Although contact lenses afford some mechanical protection for the eyes during free-fall, they will not provide complete relief from the rapid and constant airflow or from flying debris and particles in the air (Gauvreau, 1976). It is preferable for ametropic parachutists to wear contact lenses beneath protective goggles. To avoid lens dehydration resulting from rapid airflow over the eyes, sportspersons should be advised about good blinking behaviour and should be fitted with large-diameter, silicone hydrogel content lenses. High-water-content hydrogel lenses are contraindicated.

Gravitational Forces

Aerobatic pilots can be subjected to gravitational forces (G-forces) of between +6 G and −3 G. Participants in luge, bobsleigh, motor car and motor cycle racing are generally subjected to lower G-forces – typically less than +2 G. Brennan and Girvin (1985) fitted volunteer pilots with 50% and 75% water content soft lenses and subjected them to downward (z) G-forces. Lenses displaced 1.50 mm downwards in response to +4 Gz and 1.75 mm downwards in response to +6 Gz; tightly fitted lenses remained centred regardless of G-forces.

Dennis et al. (1989) observed that positive forces of up to +9 Gz caused rigid lenses to decentre downwards with a maximum decentration of 2–3 mm, without adversely affecting vision. In view of this evidence, a sportsperson who is likely to be subjected to significant G-forces may find that a large tight-fitting soft lens provides maximum stability with minimum interference to visual performance. It is estimated that 10% of sports involve the body being subjected to intermittent forces greater than +1 G.

General Considerations

The following points are of particular relevance to the prescription and aftercare management of those involved in sport:

- For young sportspersons participating in outdoor sports, prescribe minimum plus power (remember that an exact correction based on a 6-metre test distance will result in 0.17 D excess plus power, which could be problematic in time-critical acuity-dependent activities).
- Silicone hydrogel lenses worn on an extended-wear basis are indicated for sportspersons who participate in endurance events such as rally car driving, ocean racing and mountaineering, which are typically spread over weeks and months.
- In view of the known post-blink visual degradation of about 100 ms with soft lenses (Ridder and Tomlinson, 1991), spectacles are preferred to contact lenses when

critical static visual acuity is the fundamental requisite for optimum performance, especially in time-limited events (such as archery and shooting).

- The choice of correction for combination sports may involve considerable compromise if there is no pause between component events (e.g. triathlon, Nordic biathlon and Nordic combined). Conversely, various forms of correction may be used when events are spread out over many days (e.g. decathlon and modern pentathlon).
- Practitioners should be familiar with details of the particular sport or sports in which the lens wearer is participating so that the visual demands involved can be appreciated and appropriate advice offered.
- Most sports have seasonal cycles: mid-seasonal contact lens fitting or alteration should be avoided as this could provide an unnecessary distraction. For routine care, the best time is immediately following the conclusion of the season.
- Athletes often come into contact with grip resin, grease, tape dressings and ointments that are toxic to the eye and highly irritative, as well as dirt, soil or general contaminants; thus, hygiene and general compliance must be emphasized.
- The coach of a contact lens wearer should have full knowledge of the type of lenses being worn, insertion and removal techniques, the limitations of the particular lens type, the care system used, and any special constraints on lens wear, and should maintain a supply kit of lenses and solutions.
- Since contact lenses will not shield the eye from potential trauma, the usual protective eyewear or headgear used in a given sport should also be used by contact-lens-wearing sportspersons.
- Effective glare relief can be provided by sunglasses (to be worn in addition to the contact lenses) and sunshades or visors. In exceptional cases where the wearing of sunglasses is not possible – such as water sports – very dark tinted lenses (70% absorption) can provide some relief (Edmunds, 1992).
- In general, presbyopic sportspersons are less often engaged in sports that are physically demanding, such as rugby or football, and may be involved in sports such as golf that require attention to near tasks like recording and reading strategy notes (Carlson, 1990). Monovision or multifocal contact lenses are generally contraindicated, and a spectacle overcorrection for near tasks is often the best option.
- Ametropic referees are subject to the same environmental extremes and visual demands as the competitors they are adjudicating. Three main factors will govern the choice of vision correction for the ametropic referee:
    1. age – in particular, whether or not the referee is presbyopic
    2. orientation – a spectacle correction may be more suited to a static official (e.g. gymnastics) and a contact lens correction to a dynamic official (e.g. wrestling)
    3. field of vision – a static referee of a sport that is played out over a wide field of view relative to the viewing position (e.g. tennis) may prefer contact lenses.

Conclusion

A comparison of the various characteristics and attributes of soft and rigid contact lenses as well as other forms of vision correction (orthokeratology, spectacles and refractive surgery) for the sportsperson is presented in Table 25.2. Both soft and rigid contact lenses are capable of affording optimal visual function for sport. Relatively tight, large-diameter, silicone hydrogel lenses will provide the greatest in-eye stability, which appears to be an important prerequisite for the majority of sports. For certain specific activities where visual acuity is critical, such as shooting, archery and darts, spectacles may be the best option. Successful contact lens correction for sporting activities requires patience, perseverance and understanding. The reward for finding the right solution is the knowledge that the sportsperson is not hampered by ametropia and is capable of performing to his or her maximum visual capabilities.

Access the complete references list online at http://www.expertconsult.com.

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26

Keratoconus

LAURA E DOWNIE | RICHARD G LINDSAY

Introduction

Keratoconus is classically considered a bilateral, asymmetric, non-inflammatory corneal disease that is characterized by progressive thinning and steepening of the central cornea (Rabinowitz, 1998). These pathological changes lead to a relative reduction in vision secondary to the development of irregular astigmatism and/or corneal scarring (Krachmer et al., 1984). Keratoconus is the most highly prevalent primary corneal ectasia, affecting an estimated 54 per 100 000 people (Kennedy et al., 1986). Although the aetiology of keratoconus remains uncertain, it is recognized to be a multifactorial condition, involving genetic, biochemical and/or environmental factors (Davidson et al., 2014).

Contact lens practitioners play a vital role in providing appropriate optical appliances to delay, or even preclude, the need for keratoplasty in people with keratoconus. The first application of contact lenses for keratoconus was described by the German-born physician and physiologist, Adolf Fick, in 1888 (Efron and Pearson, 1988). In more recent times, advances in contact lens designs and materials have expanded the fitting options for patients with corneal ectasia. These developments are underpinned by the need for contact lenses not only to deliver the desired improvement to vision, but also to provide appropriate levels of comfort and to maintain corneal physiology.

This chapter provides a comprehensive overview of the range of contemporary contact lens modalities, including soft, rigid (i.e. corneal, corneo-scleral, miniscleral and scleral lenses), hybrid and piggyback designs, that are available for the optical management of keratoconus. The application of anterior-segment imaging technologies, including corneal topography and optical coherence tomography (OCT), to assist with contact lens fitting is also considered. Furthermore, the importance of monitoring for disease progression in people with keratoconus, particularly children, is discussed.

Keratoconus Clinical Assessment

Robust baseline clinical data are essential both for monitoring disease progression and for guiding contact lens management in people with keratoconus. While several keratoconus classification systems have been proposed, based upon various criteria that include corneal morphology, clinical signs, topographical parameters and/or corneal structural changes (Amsler, 1938; Perry et al., 1980; Maeda et al., 1994; Rabinowitz and Rasheed, 1999; McMahon et al., 2006; Mahmoud et al., 2008; Sandali et al., 2013), there remains a lack of a universally accepted keratoconus severity staging scale for either research or clinical purposes.

ANTERIOR SEGMENT IMAGING TECHNOLOGIES

Contemporary imaging technologies have significantly enhanced the capacity to image the cornea in clinical practice (see Chapter 41). Compared with traditional keratometry, Placido-disc-based corneal topography facilitates relatively earlier diagnosis and enhanced disease monitoring of keratoconus (Maguire and Lowry, 1991; Wilson and Klyce, 1994). A range of quantitative topographic indices exist to identify anomalies of corneal curvature that indicate for corneal ectasia (Wilson and Klyce, 1994; Mahmoud et al., 2008; Downie, 2011; Sandali et al., 2013).

More recently, imaging systems that do not rely upon the quality of the surface image, such as optical coherence tomography (OCT), have emerged and have clinical application both for assessing in vivo corneal microstructural changes and guiding contact lens fitting. An OCT-based keratoconus classification system, that was reported to also provide a grading of severity, has been described (Sandali et al., 2013). Further clinical studies, over follow-up periods that are sufficient to evaluate the natural history of classification using this OCT system, are still required to validate this method of disease categorization. Anterior segment OCT has been used to quantify post-lens tear film clearance patterns in rigid corneal lens relationships (i.e. three-point-touch, apical clearance and apical bearing) (Elbendary and Abou Samra, 2013). The application of OCT for fitting miniscleral lenses is discussed in the ‘miniscleral lens’ section of this chapter.

KERATOCONUS CONE MORPHOLOGY

Based upon morphological criteria, three major subtypes of keratoconus are recognized (Fig. 26.1) (Perry et al., 1980; McMahon et al., 2006). Although the prevalence of these subtypes can vary in different demographics, centred (nipple) cones are considered to account for about half of morphologies; this subtype is characterized by a cone diameter of 5 mm or less that is round and positioned centrally or slightly inferior to the geometric centre of the cornea. Oval (sagging) cones are larger in diameter and demonstrate either infero-nasal or infero-temporal displacement of the corneal apex. As rigid contact lenses tend to align over the corneal apex, achieving adequate lens centration and pupil coverage for oval cones can pose a relative challenge (Perry et al., 1980; Romero-Jimenez et al., 2010; Downie, 2011). Commonly regarded as the least common cone morphology is the globus cone, in which the conical area involves at least 75% of the cornea. From a contact-lens-fitting perspective, these cases are arguably the most complex and typically warrant designs with larger diameters to achieve a desired fitting.

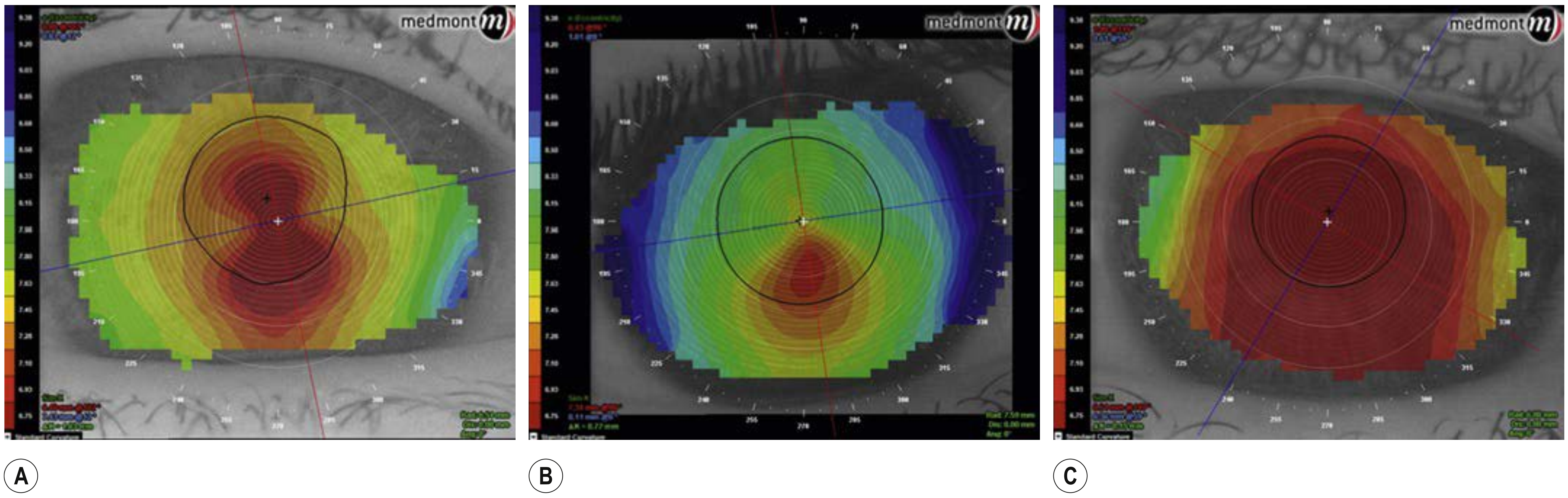

Fig. 26.1 Corneal axial power topography maps, with normalized power scales (in dioptres), showing the three major cone morphologies in keratoconus. (A) A nipple cone consisting of localized steepening at the corneal apex. (B) A sagging cone with corneal steepening positioned inferior to the corneal geometric centre. (C) A globus cone showing a large area of corneal steepening.

BOX 26.1 NON-SURGICAL REFRACTIVE MANAGEMENT OPTIONS FOR KERATOCONUS

- Spectacles
- Contact lenses
  - Soft
  - Rigid
    - Corneal
    - Corneo-scleral
    - Miniscleral
    - Scleral
  - Hybrid
  - Piggyback

ANTERIOR OCULAR HEALTH

An additional important element of the clinical assessment of people with keratoconus, particularly in the context of contact lens fitting, is the diagnosis and management of comorbid ocular conditions. Associations between keratoconus and atopic disease, including eczema, asthma and rhinoconjunctivitis, are well known (Rahi et al., 1977; Harrison et al., 1989; Kaya et al., 2007; Downie, 2014a). Allergic and / or dry eye disease can be major impediments to successful contact lens wear and therefore require timely and appropriate ophthalmic care prior to the commencement of contact lens wear (Zhou et al., 2003).

Refractive Management of Keratoconus

The management of keratoconus will vary depending upon the severity of the disease. Refractive management options are largely non-surgical, with contact lens correction often being essential to achieving the best functional outcomes. Box 26.1 provides a summary of the major forms of visual correction that are currently available in clinical practice for the non-surgical management of keratoconus; each of these modalities is elaborated upon in this chapter.

SPECTACLE CORRECTION

Spectacle correction may provide adequate visual correction in earlier stages of keratoconus and / or be of value as an adjunct to contact lenses when an appropriate level of functional spectacle acuity can be achieved. Retinoscopic findings can assist the practitioner with determining an appropriate starting point for subjective refraction. Refraction should be undertaken judiciously, as people with keratoconus may have difficulty with subjective determinations of refractive end-points; this is probably due to the multifocal nature of the cornea (Camp et al., 1990) and is an effect that is heightened with advanced disease. In undertaking subjective refraction, relatively large refractive steps (e.g. ±1.00 to ±3.00 D) may need to be presented to the patient to enable subjective differences to be discernable. Whenever practicable, and particularly at baseline, best corrected spectacle acuity should be recorded to serve as a reference point for longitudinally evaluating significant changes to visual function.

The use of a spectacle correction for the optical management of keratoconus often has some notable limitations, however. Subjective refraction can be poorly repeatable (Raasch et al., 2001) or, particularly as in cases of more advanced keratoconus, simply not feasible to perform. Progressive disease can lead to rapid changes to the refraction, with refractive shifts possible over periods of weeks, which can render a relatively recent spectacle correction suboptimal. Consideration with regard to the likelihood of patient tolerance to high degrees of refractive astigmatism, particularly in the context of anisometropic refractions, is also required. Given these factors and the potential for enhanced irregular astigmatism correction with many contact lens modalities, contact lenses remain the predominant optical corrective modality for keratoconus.

SOFT LENSES

Soft contact lenses, typically in disposable form, are a useful visual correction option for forme fruste and / or earlier forms of keratoconus (Griffiths et al., 1998). Soft lenses may also provide a suitable form of contact lens correction for people with keratoconus who have implanted intrastromal corneal ring segments (ICRS) (Fernandez-Velazquez and Fernandez-Fidalgo, 2015; Romero-Jimenez et al., 2015). Similar to spectacle correction, a major shortcoming of this modality is the inability to mask irregular corneal astigmatism (Griffiths et al., 1998; Jinabhai et al., 2012). One small study involving 13 individuals with different stages of keratoconus showed that spherical hydrogel soft lenses provide poorer high- and low-contrast visual acuities than does rigid corneal lens correction (Griffiths et al., 1998). Similar findings were reported in another clinical investigation, whereby rigid corneal lenses were found to provide relatively enhanced low-contrast acuity and a reduction in higher-order aberrations compared with toric hydrogel soft contact lenses (Jinabhai et al., 2012). In this study, visual performance with soft toric lenses was reported to be comparable to that measured with a spectacle correction (Jinabhai et al., 2012). Refereed studies comparing the visual efficacy of soft contact lenses made from silicone hydrogel materials with rigid lens designs for keratoconus are currently lacking. It has been suggested that the modulus of elasticity of silicone hydrogel lenses, being greater than that of hydrogel materials, may enable these lenses to have relatively improved conformational integrity in situ, and thereby provide enhanced / or more stable visual acuity. Studies to clarify whether such an advantage exists are still needed.

Major advantages of soft contact lenses over traditional rigid lens correction are the enhanced on-eye comfort profile and the relative ease of fitting (Koliopoulous and Tragakis, 1981). Compared with spectacles, there are also potential benefits of adopting contact lenses in relation to improved quality of life in young adults (Pesudovs et al., 2006). Consideration of on-eye comfort is pertinent in the context of any prior history of rigid lens intolerance and / or when rigid lenses are deemed impractical. Factors that may influence the practicality of rigid lens correction include ocular (e.g. monocular correction), occupational (e.g. dusty working environment) and recreational (e.g. participation in dynamic sporting activities) considerations. From the clinician's perspective, a soft lens fitting procedure for a person with keratoconus essentially mirrors the process that is routinely applied to eyes without irregular astigmatism (see Chapter 8). Depending upon the extent of corneal irregularity, the soft lens parameters may need to be carefully selected to ensure adequate on-eye lens movement. The soft lens material should also be selected so as to minimize the likelihood of corneal hypoxic complications, such as corneal neovascularization, which may complicate a future keratoplasty procedure.

In recent years, the ability to lathe quadrant-specific curve designs in soft lens materials has supported the development keratoconus-specific soft contact lenses (e.g. KeraSoft IC, Bausch & Lomb; Soft K, Soflex; NovaKone, Alden Optical). At present there is a relative paucity of published data regarding the clinical efficacy of these designs. One case series, involving two people, reported on the use of the Soft K lens design for optical correction of mild keratoconus (Gonzalez-Meijome et al., 2006). A retrospective analysis comparing visual acuity outcomes in keratoconus eyes with mild to moderate ectasia that had been fitted with either the silicone hydrogel KeraSoft IC lens (n = 94) or the Menicon Rose-K2 rigid lens (n = 94), reported no significant difference between lens types (Fernandez-Velazquez, 2012). A case series describing the successful fitting of KeraSoft IC lenses to eyes implanted with ICRS has also been recently published (Fernandez-Velazquez and Fernandez-Fidalgo, 2015).

Computer-based simulations suggest that customized correction of lower- and higher-order ocular aberrations, notwithstanding contact lens movement in situ, should benefit visual function in keratoconus (Guirao et al., 2001; de Brabander et al., 2003). In recent years, a number of custom aberration-controlled soft contact lens designs have been developed and have undergone varying degrees of investigation (Marsack et al., 2007a; Sabesan et al., 2007; Marsack et al., 2008; Jinabhai et al., 2014). Although significant reductions to overall ocular aberrations have been demonstrated, the success of these soft lens modalities varies between individuals with keratoconus (Jinabhai et al., 2014). Such variability may be attributable to a range of factors, including keratoconus severity, cone morphology and the magnitude and consistency of any lens translation in situ. At present, further research is needed to determine the clinical applicability of customized, aberration-controlled soft contact lenses for mainstream keratoconus management.

TABLE 26.1 Rigid Contact Lens Nomenclature

Lens Classification	Diameter (mm)
Corneal	7.0–12.0
Corneo-scleral	12.1–15.0
Minisceral	15.1–18.0
Scleral	>18.0

(Reproduced from Downie & Lindsay, 2015.)

RIGID LENSES

Rigid contact lenses, both prior to and since the availability of gas-permeable materials, have been the primary form of visual correction for keratoconus (Rabinowitz, 1998; Zadnik et al., 1998; Weed et al., 2007). In maintaining their on-eye conformation, rigid lenses create a lacrimal lens between the irregular anterior corneal surface and posterior lens surface that neutralizes much of the corneal astigmatic error, but will not necessarily normalize higher order aberrations (Marsack et al., 2007b; Negishi et al., 2007).

Rigid lens classification is typically based upon differences in lens total diameter (TD), as summarized in Table 26.1, although specific terminology can vary. It should also be noted that this classification is dependent on the size of the cornea. For example, if a patient has microcornea with a corneal diameter of 9.0 mm, then in this case a rigid lens with a total diameter of 10.0 mm could arguably be considered a corneo-scleral lens in situ.

Corneal lenses have been the most common form of rigid lens utilized for keratoconus for the past few decades (Morgan et al., 2016). Over this time, the use of scleral lenses has become less frequent. However, recently contact lens practice has witnessed the re-emergence of other larger-diameter rigid lens modalities, in the form of corneo-scleral and miniscleral lenses. The prescription of these alternative rigid lens forms for the contact lens management of keratoconus has increased significantly in recent years owing to the associated advantages of larger-diameter contact lenses, which include enhanced on-eye comfort and stability (van der Worp, 2010a).

Corneal Lenses

A diverse range of commercial corneal lens designs exist for keratoconus, including spherical multicurve and aspheric designs. Corneal lenses can also be custom designed by the practitioner, on a case-by-case basis. Most studies that have evaluated rigid lens correction with corneal lenses in keratoconus have involved retrospective analyses in specific clinical populations.

These studies (Betts et al., 2002; Lim and Vogt, 2002; Zadnik et al., 2005; Szczotka-Flynn and Patel, 2008; Yanai et al., 2013) provide insight into the range of corneal lens designs that have been utilized in practice for the optical correction of keratoconus. However, objective comparisons between lens designs are not possible in the absence of a suitable control group and/or clearly defined criteria regarding the definition of a 'successful' lens fitting. There is currently a lack of high-quality, controlled prospective clinical evidence to inform clinical decisions regarding the relative merit of different proprietary keratoconus lens designs.

Fitting Philosophies. As discussed in Chapter 15, traditionally the clinical evaluation of rigid lens fitting is facilitated by the application of sodium fluorescein to the eye and the subsequent observance of the fluorescence pattern beneath the contact lens. A Wratten 12 barrier filter, or similar, placed in front of the slit-lamp biomicroscope objective, can significantly enhance sodium fluorescein pattern assessment. Using sodium fluorescein patterns, three major philosophies for fitting corneal lenses to eyes with keratoconus are recognized (Korb et al., 1982; Leung, 1999): apical bearing, apical clearance and three-point touch.

Apical Bearing. In an 'apical-bearing' fitting relationship, the primary support of the rigid lens is directly on the corneal apex. This results in a sodium fluorescein pattern that has a central darkened region, which corresponds to the back optic zone diameter (BOZD) of the lens (Fig. 26.2A). Historically, it was incorrectly hypothesized that this fitting philosophy could retard keratoconus progression by imparting physical resistance to progressive corneal deformation. It is now recognized that any apparent flattening effect on the corneal apex is transient and not of value for attenuating progressive corneal ectasia (Woodward, 1997).

Clinically, a primary concern with this mode of fitting is the potential for axial corneal scarring, subsequent to long-term abrasive contact between the rigid lens and the cornea. It is important to note that central corneal scarring may occur in the absence (Krachmer et al., 1984) (Fig. 26.2B) or presence (Korb et al., 1982) (Fig. 26.2C) of contact lens wear in keratoconus. It is, however, possible that contact lens wear is an exacerbating factor that hastens the pathology (Zadnik et al., 2005). Harsh apical lens bearing can result in significant corneal epithelial disruption, which is clinically identifiable by a 'whorl'-type staining pattern (Fig. 26.2D). This apical epithelial breakdown may progress to corneal scarring in the scenario that an excessively flat-fitting rigid lens is worn for a prolonged period of time (Korb et al., 1982).

Apical Clearance. An 'apical clearance' rigid lens fitting features complete clearance of the corneal apex, with lens support (landing) on the paracentral cornea (Fig. 26.2E) (Voss and Liberatore, 1962). This approach is achieved by fitting the back optic zone radius (BOZR) of the lens relatively steeper than the apical corneal curvature. The rationale behind this fitting philosophy is that it should minimize direct corneal epithelial trauma and the subsequent long-term risk of corneal scarring (Korb et al., 1982; Leung, 1999). There is however, still the potential for transient corneal-moulding effects, peripheral corneal disruption and lens binding (Zadnik et al., 2005).

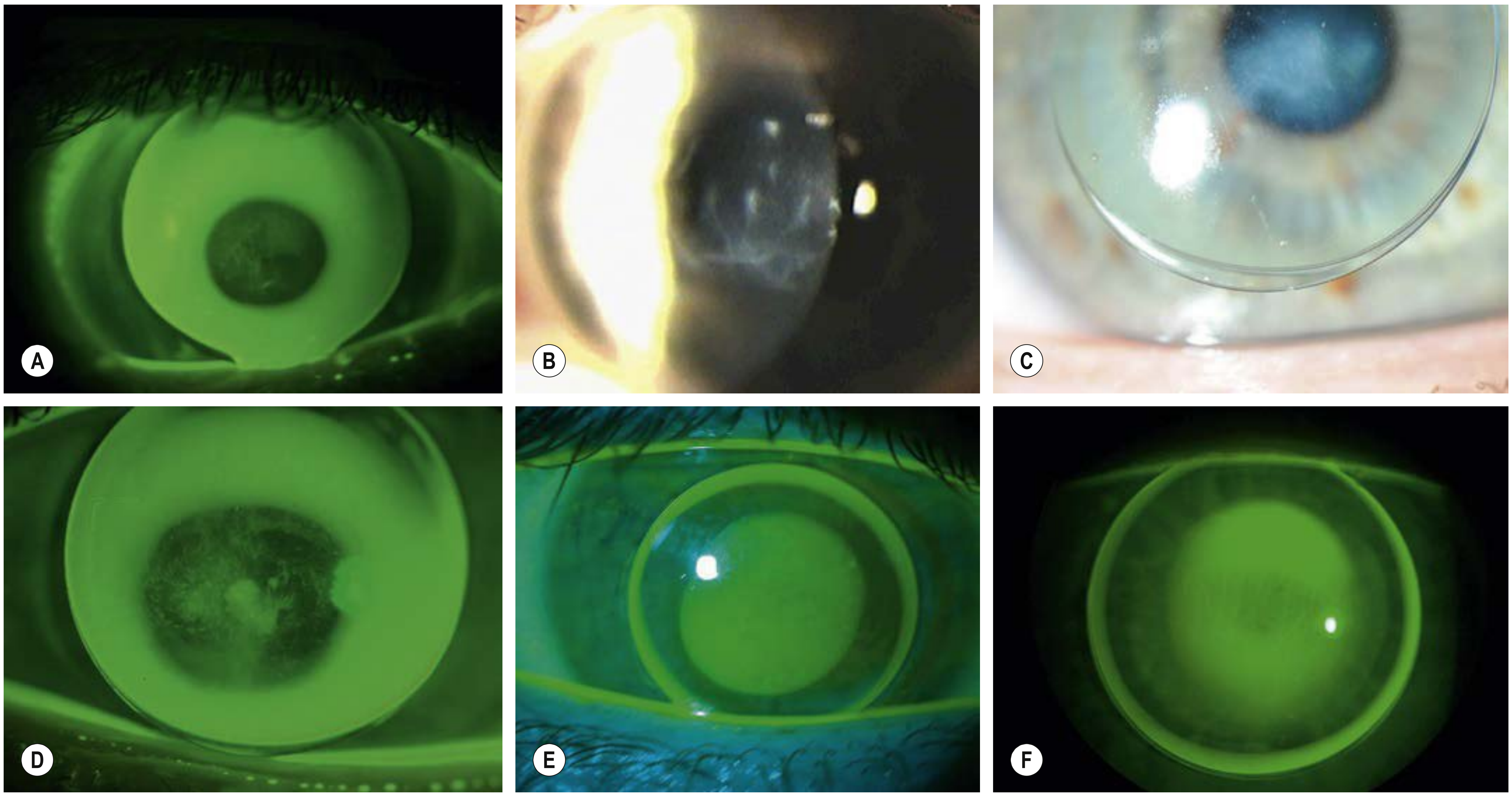

Fig. 26.2 Rigid contact lens fitting in keratoconus. (A) An 'apical bearing' rigid lens fitting with significant bearing on the corneal apex. (B) Apical corneal scarring in a keratoconus patient who has never worn contact lenses. (C) Dense apical corneal scarring in a patient wearing a relatively flat fitting rigid lens. (D) 'Whorl'-type corneal staining and epithelial damage, subsequent to harsh apical bearing with a rigid lens. (E) An 'apical clearance' rigid lens fitting with visible clearance (vaulting) of the corneal apex. (F) A 'three-point touch' rigid lens fitting with an apparent subtle darkening of the fluorescein profile over the corneal apex. (From Downie and Lindsay (2015) and used with permission from Clinical and Experimental Optometry.)

The Collaborative Longitudinal Evaluation of Keratoconus (CLEK) study developed a standardized approach to apical clearance corneal lens fitting, whereby the end-point of the process was the flattest BOZR that showed definite apical clearance using sodium fluorescein assessment. Based upon the results of this study, the conclusion was made, despite absence of a control group, that fitting rigid corneal lenses with apical clearance was preferred for keratoconus (Zadnik et al., 2005). Although the CLEK study reported superior visual acuity with relatively steep-fitting corneal lenses (Zadnik et al., 2005), the association between better visual outcomes and apical clearance fitting remains unclear (Voss and Liberatore, 1962). Whether apical clearance rigid lens fitting affects keratoconus progression is also uncertain. It has been postulated that apical clearance fittings may actually increase the risk of progression in early keratoconus, especially given that with corneal moulding there is a tendency for the corneal curvature to shift towards the contact lens BOZR (McMonnies, 2004).

Three-point Touch. For a 'three-point-touch' corneal lens fitting, the aim is to have 'apparent touch' at the corneal apex (evident as a subtle reduction in the brightness of the sodium fluorescein), with the majority of the lens-bearing pressure residing on the peripheral cornea (Fig. 26.2F). The term 'apparent touch' intends to reflect the lack of true physical interaction between the lens and the corneal apex; the relative darkening of the sodium fluorescein profile in this zone is the consequence of a tear lens thickness below 20 µm, being the approximate threshold for fluorescence. This method of fitting rigid corneal lenses to keratoconus eyes has previously been shown to be popular amongst contact lens practitioners (Mandell, 1997; Zadnik et al., 1998). The key factor with this approach is to ensure that the contact lens does not bear heavily on the corneal apex so as to cause an epithelial abrasion (Mandell, 1997). In practice, a three-point-touch fitting pattern that tends towards apical clearance is probably optimal, as it allows both for keratoconus progression and/or for potential non-compliance with respect to clinical follow-up (Leung, 1999).

Lens Designs

Spherical Lens Designs. Many rigid lens designs have been developed for keratoconus. Most of these designs aim to provide a steeper than typical BOZR, to accommodate the conical nature of the central cornea, and then incorporate a series of peripheral curves with progressively flatter radii to clear the relatively normal peripheral cornea (Caroline and Andre, 1998). Due to the relatively steeper BOZR, there needs to be relatively more flattening of the peripheral curves to achieve an acceptable degree, about 0.08–0.1 mm, of edge clearance (Woodward, 1997). That a greater degree of flattening is warranted in the lens periphery is reflected by the relatively high corneal eccentricity values, consistent with a relatively prolate corneal shape, being a clinical feature of keratoconus.

The multicurve lens, consisting of multiple spherical radii that are blended together to form the desired flattening contour, is a common rigid lens design for keratoconus (Lee and Kim, 2004). Multicurve lenses have the advantage of readily changeable parameters, including BOZR, TD, BOZD, back peripheral curve radii (BPR) and back peripheral curve widths (Lee and Kim, 2004). Flexibility to customize these parameters is important, as the contact lens practitioner will often need to modify, and typically more than once, some or all of these parameters before determining the optimal contact lens prescription. It is therefore essential for the practitioner to have access to an appropriate keratoconus rigid lens fitting set for this purpose (Zadnik et al., 2005).

Consider the following three typical corneal rigid lens specifications for keratoconus:

Lens 1	C4/6.80:6.40/7.60:7.20/8.40:8.00/10.20:8.80	−7.00	AEL 0.23
Lens 2	C4/6.20:6.00/7.10:6.80/8.20:7.60/10.40:8.40	−11.00	AEL 0.31
Lens 3	C4/5.60:5.60/6.60:6.40/8.10:7.20/10.60:8.00	−15.00	AEL 0.38

Of the three lenses, lens 1 shows parameters for the relatively earliest stage of keratoconus. Lenses 2 and 3 incorporate parameters for increasingly more severe disease, respectively. Note that, with increasing keratoconus severity, greater axial edge lift (AEL) of the contact lens is required to achieve an acceptable degree of edge clearance; this is the consequence of the steeper BOZR.

These three rigid lens specifications also demonstrate some other important fitting principles with respect to corneal lenses and keratoconus. First, the TD generally decreases as the keratoconus progresses. Second, the more advanced the keratoconus, the smaller will be the BOZD; this is primarily to facilitate adequate tear exchange around the apex of the cone, which in turn will assist with preventing tear pooling and accumulation of tear debris under the optic zone of the lens. Finally, the required back vertex power (BVP) of the lens will be more negative (i.e. higher minus) as the keratoconus progresses owing to the effect of the tear lens becoming more positive when fitting a steeper BOZR.

There are a couple of important points to note in relation to rigid lens BVPs. First, the higher minus power that is usually associated with a keratoconic contact lens prescription does not imply that the patient is highly myopic, although this mistake is often made in clinical practice. Indeed, for the three lenses previously specified, the BVPs of −7.00, −11.00 and −15.00 would actually be more typical of patients with keratoconus who are also relatively emmetropic based on the corresponding BOZRs of 6.80 mm, 6.20 mm and 5.60 mm, respectively. A person with keratoconus can also have associated myopia or hyperopia; in this case, the BVP in the contact lens prescription would be different from what is normally predicted according to the BOZR.

Second, with regard to taking into account the change in tear lens power that will occur as a result of changing the BOZR, it was noted in Chapter 16 that, as an approximation, for every 0.05 mm decrease (steepening) in BOZR, −0.25 D must be added to the BVP of the contact lens. Similarly, +0.25 D should be added to the BVP of the contact lens for every 0.05 mm increase (flattening) in BOZR. However, this approximation does not hold for BOZR steeper than 7.00 mm, even for small changes in BOZR. For keratoconus, it is therefore more accurate to use the tear lens formulae outlined in Chapter 16 to calculate the required BVP following BOZR modification.

For example, let us consider the compensatory change to BVP that is required when a rigid lens BOZR is steepened by a relatively small amount, from 6.70 mm to 6.60 mm. According to the approximation, we would add −0.50

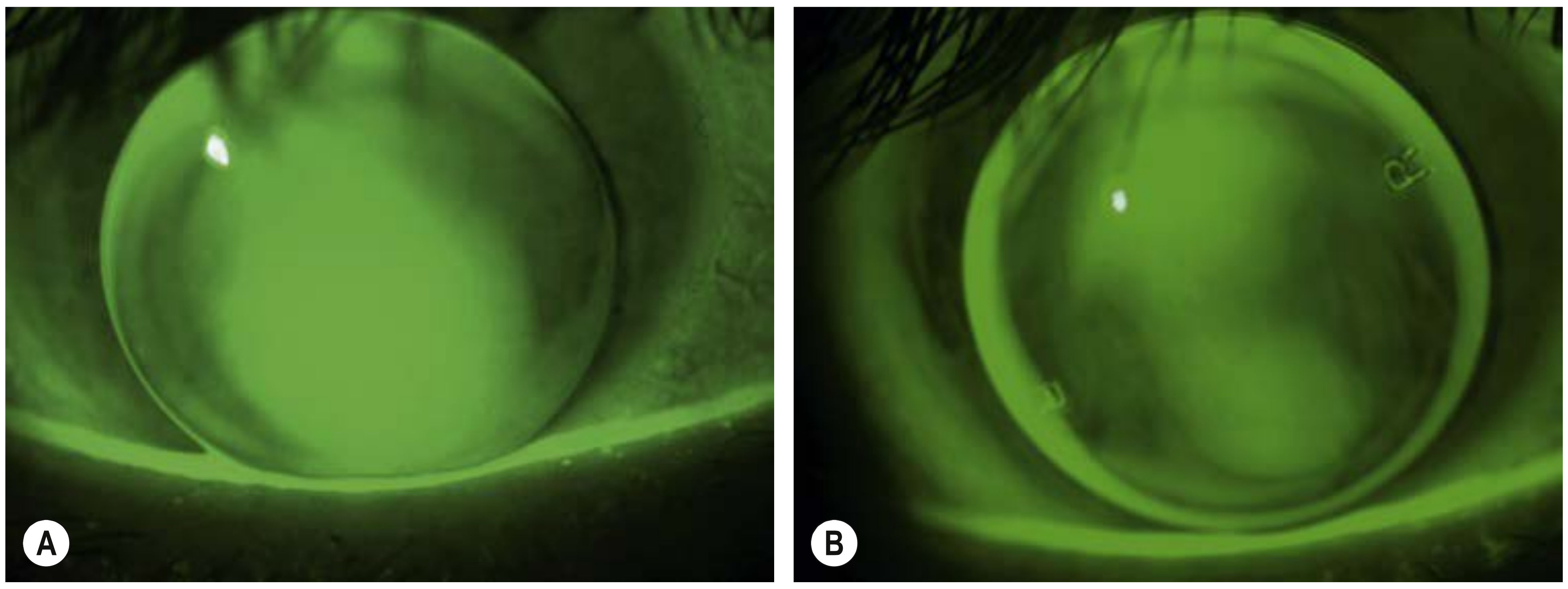

Fig. 26.3 Rigid contact lenses with spherical and toroidal peripheral curves. (A) A sodium fluorescein photograph of a rigid contact lens with a spherical periphery, on an eye with keratoconus; the lens edge clearance is greater along the vertical meridian than the horizontal meridian due to the peripheral with-the-rule astigmatism. (B) A sodium fluorescein photograph of a rigid contact lens with toroidal peripheral curves on the same eye, showing symmetric edge clearance around the circumference of the lens.

D to the BVP of the rigid contact lens. However, using tear lens formulae, we see that we actually need to add $(336/6.70-336/6.60) \approx -0.75$ D to the BVP. The magnitude of this error increases with increasingly steep BOZR. For example, using the approximation for a change in BOZR from 5.90 mm to 5.80 mm gives a suggested increase in BVP of −0.50 D; however, actual calculation shows that the BVP should be adjusted by −1.00 D.

Aspheric Lens Designs. Considerable improvements in manufacturing and technology, such as precision aspheric lathing, mean that rigid aspheric lenses also have application for the contact lens management of keratoconus (Caroline and Andre, 1998). Aspheric rigid corneal lenses are typically fitted nominally steeper than multicurve lenses in relation to the corneal curvature; however, their sagittal height is usually less than a multicurve lens owing to the relationship between the nominal BOZR and the lens eccentricity (Lee and Kim, 2004). TD is an important fitting factor in aspheric designs as it has to be manipulated, as a result of the base curve–eccentricity value relationship, to maintain the desired degree of edge clearance (Bennett, 1986); smaller lens diameters will give greater edge clearance, whereas larger lens diameters will provide relatively less edge clearance.

Toroidal Lens Designs. Due to the highly irregular and asymmetric astigmatism that is characteristic of keratoconus, rigid corneal lenses with toroidal BOZR should be fitted sparingly (Woodward, 1997). A rigid lens with toroidal BOZR will generally locate poorly on a keratoconic cornea, with excessive on-eye rotation. Notably, the peripheral corneal curvature in keratoconus is often relatively asymmetric and can have significant regular astigmatism; this is most commonly with-the-rule astigmatism. In such cases, the edge clearance will be more generous along the vertical meridian compared with the horizontal meridian (Fig. 26.3A); the quality of the peripheral fitting relationship can be enhanced with the use of toroidal peripheral curves (Fig. 26.3B).

Let us assume that the rigid lens shown in Fig. 26.3A incorporates the following parameters:

$$\text{C4/6.70:6.40/7.40:7.20/8.30:8.00/10.10:8.80} \quad -7.50$$

Then, using the notation shown in Chapter 16 for specification of a rigid lens with a spheroidal optic zone and a toroidal back optic zone, the lens shown in Fig. 26.3B might have the following specification:

$$\text{C4/6.70:6.40}\Big/\frac{7.10}{7\ 80}:7.20\Big/\frac{8.00}{8.70}:8.00\Big/\frac{9.80}{10.50}:8.80 \quad -7.50$$

In this case, the relatively flatter peripheral curves (7.80 mm, 8.70 mm and 10.50 mm) will align along the (flatter) horizontal corneal meridian and the relatively steeper peripheral curves (7.10 mm, 8.00 mm and 9.80 mm) will align along the (steeper) vertical corneal meridian.

If a patient with keratoconus also has significant residual astigmatism, defined as the non-corneal component of the ocular astigmatism (Lindsay et al., 2013), a front-surface toric rigid lens (incorporating a spherical BOZR and a toroidal front surface, and is discussed in Chapter 16) can be considered. As a front-surface toric rigid lens design would also require a prism ballast for apposite lens stabilization, which may compromise the fitting in more advanced cases of keratoconus, spectacles (worn over the contact lens correction and incorporating the residual cylinder) are often the preferred mode of correction.

The development of quadrant-specific designs has been another important innovation that has extended the range of available contact lens options for keratoconus. Quadrant-specific designs enable a different edge lift to be incorporated into each lens quadrant. This lens design is useful for keratoconus as there is typically significant asymmetry in the peripheral corneal contour (van der Worp, 2010b). The most frequent application of quadrant-specific designs in keratoconus is for inferiorly displaced sagging cones; the inferior lens quadrant can be designed to incorporate relatively reduced edge lift, in order to minimize inferior lens stand-off and interaction with the inferior eyelid.

Placido-disc corneal topography, which was discussed in the context of keratoconus diagnosis earlier in this chapter, can also be of clinical value for rigid lens fitting. Corneal topography-derived radii of curvature data can assist the practitioner when selecting an initial BOZR for rigid lens trial fitting. In a study of 35 eyes with keratoconus, the final rigid lens BOZR was found to correlate with the steep axial curvature value obtained from Placido-based videokeratography (Szczotka and Thomas, 1998). An alternative approach is to begin a diagnostic fitting with an initial BOZR that is midway between the steep and flat keratometry values (Edrington et al., 1999). Tangential corneal maps

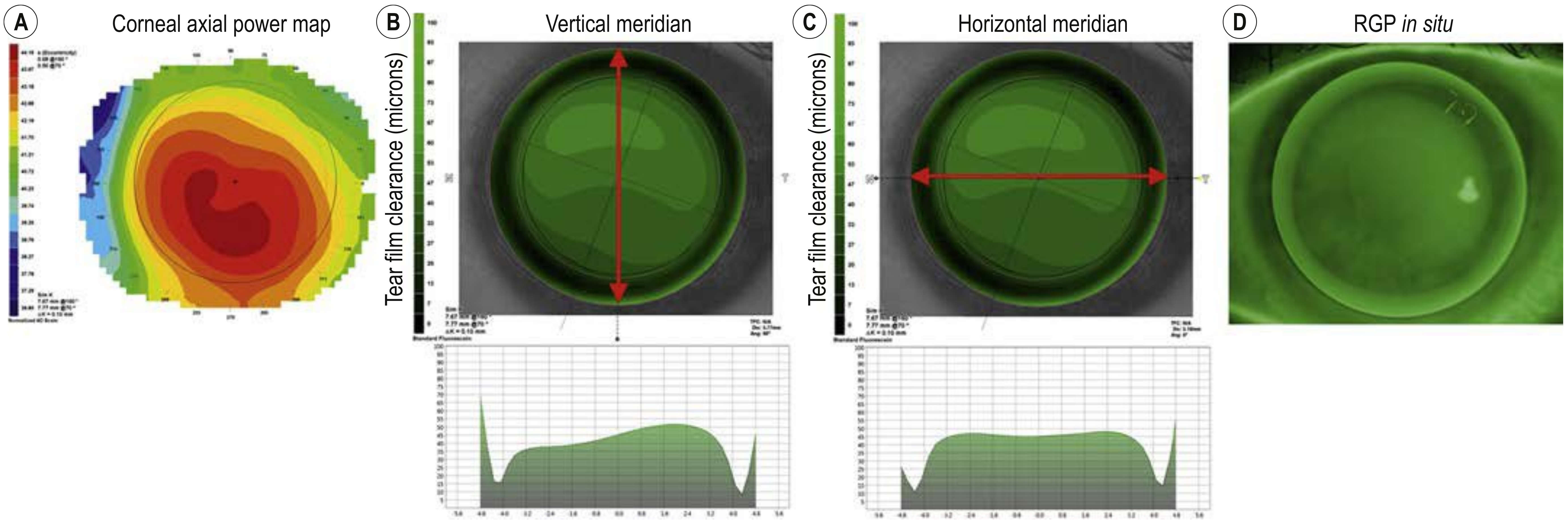

Fig. 26.4 Virtual (simulated) rigid contact lens fitting. (A) Corneal axial power map, derived from Placido-disc-based videokeratography, with normalized scale (in dioptres). Simulated sodium fluorescein pattern, showing the predicted tear film clearance for the chosen rigid lens design along both the (B) vertical and (C) horizontal meridians (red arrows). (D) A sodium fluorescein photograph of the actual rigid lens in situ shows a strong resemblance to the simulated fitting pattern. (From Downie and Lindsay (2015) and used with permission from Clinical and Experimental Optometry.)

can be used to quantify the size and location of the cone, which assist with selecting an appropriate BOZD and TD (Sorbara and Dalton, 2010). Similar application of topographic-derived data has been reported to be of predictive value for fitting hybrid lenses in keratoconus (Downie, 2013).

Virtual contact-lens-fitting software, available within many videokeratoscopic systems, can be used for modelling the effect(s) of altering lens parameters on the on-eye fitting characteristics of a range of different lenses (Fig. 26.4). A 1-year prospective study that compared the use of a computerized videokeratography system with standard diagnostic procedures for fitting rigid corneal lenses to patients with corneal ectasia showed relatively enhanced success and efficiency with the simulation system (Nosch et al., 2007). Sindt et al. (2011) assessed the degree of similarity between theoretical sodium fluorescein patterns derived from the Medmont E300 corneal topographer (Precision Technology, Canada) contact lens simulator with actual fitting patterns observed at the slit-lamp biomicroscope for 31 rigid lens fittings for keratoconus. Accurate prediction of the sodium fluorescein pattern was reported in 74% of cases; the degree of concordance was found to be dependent upon the quality of the captured Placido-disc imagery.

Corneo-scleral Lenses

In corneo-scleral designs, lens bearing is shared between the sclera and the cornea (Bennett, 1986). As for other larger-diameter rigid contact lenses, the major potential advantages of these designs compared with corneal lenses are enhanced comfort, a larger BOZD to facilitate more consistent visual performance and improved on-eye stability (Downie, 2014b). Corneo-scleral designs can be particularly useful for fitting inferiorly displaced sagging cones and, similarly, eyes with pellucid marginal degeneration (Fig. 26.5) where the corneal apex is markedly inferior due to the presence of corneal thinning in close proximity to the limbus (Lindsay, 1993).

In contrast to miniscleral designs, corneo-scleral lenses exhibit on-eye movement and provide a moderate amount of tear exchange (i.e. they are not a 'sealed' fit). Consequently, fenestrations are not required for corneo-scleral lenses and, in many respects, the fitting approach is similar to that of a corneal rigid lens. Corneo-scleral lenses can also incorporate the complement of design features (i.e. multicurve, aspheric, toric and quadrant specific) that were described in the previous section on corneal lenses.

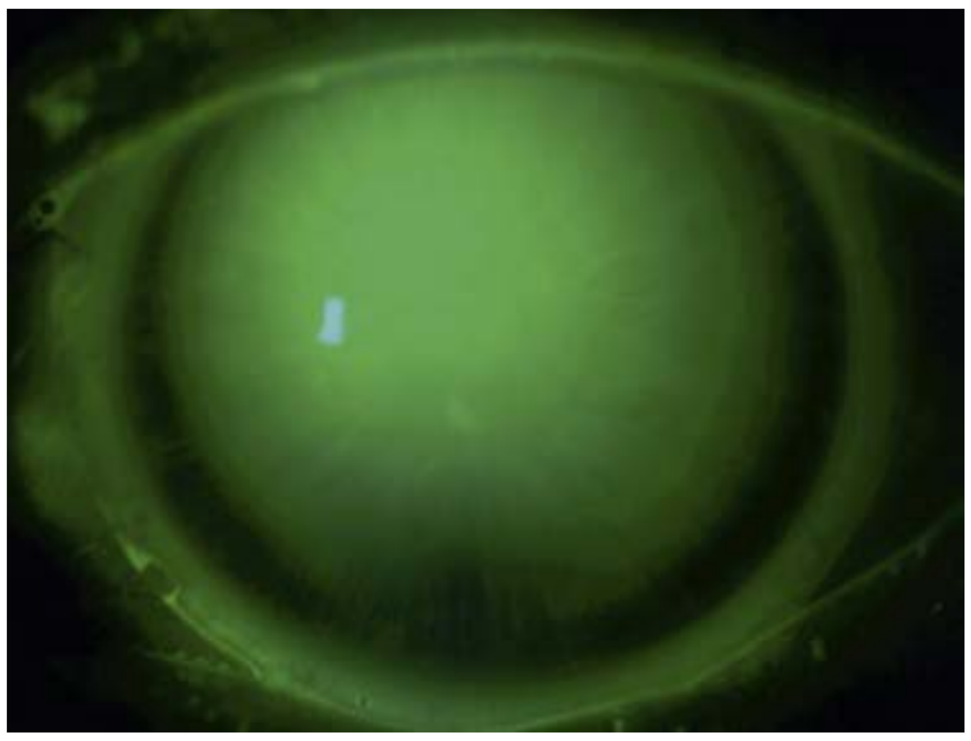

Fig. 26.5 A corneo-scleral contact lens on an eye with pellucid marginal degeneration. Sodium fluorescein photograph of a 14.60 mm Rose K2 XL corneo-scleral contact lens in situ. (Courtesy of Paul Rose.)

Oxygen transmissibility (Dk/t) through a corneo-scleral lens is also generally higher than that through a miniscleral lens owing to the thinner tear layer associated with the former (usually less than 50 µm compared with in excess of 200 µm). As for corneal rigid lenses, corneo-scleral lenses must be fitted to ensure that there is adequate peripheral lens clearance. Furthermore, limbal compression by the lens must be avoided with larger-diameter rigid lenses, as it can be a major stimulus for angiogenesis (Efron, 1987).

Miniscleral Lenses

Similar to corneo-scleral lenses, miniscleral lenses have the advantages of enhanced on-eye comfort and stability; these factors have most likely contributed to the rapid increase in the popularity of these designs in recent years. When fitted appropriately, miniscleral lenses should vault both the cornea and limbus, with an evenly distributed weight on the sclera (Watanabe, 2013). Generally, miniscleral lenses are fitted to achieve a semi-sealed state, with partial tear exchange (van der Worp, 2010a). The lens must not rest on the limbus and the scleral fit should not be so tight that the lens shifts from a semi-sealed to a sealed state, as this can prevent tear exchange and lead to both short-term (Bruce and Nguyen, 2013) and long-term (DeNaeyer, 2012) complications. These lenses need to be filled with an appropriate ophthalmic solution, usually unit-dose or non-preserved saline, prior to their application in order to prevent air bubble formation beneath the lens (Gromacki, 2013). This is similar to the technique advocated and successfully adopted by Pullum for scleral lenses (Pullum, 1997) (see Chapter 21).

Upon initial application to the eye, a miniscleral lens should vault (clear) the corneal apex by approximately 300 µm (Caroline and Andre, 2011). The lens should rest onto the bulbar conjunctiva and Tenon's capsule, both being relatively soft ocular tissues. As a result, the extent of corneal clearance (also termed 'corneal vault') will reduce as the miniscleral lens settles and compresses these tissues. This lens settling effect can induce a decrease in corneal vault of between 70 and 180 µm (Caroline and Andre, 2012; Kauffman et al., 2014) and therefore needs to be accounted for during lens fitting. Once settled onto the eye, the lens should have a central clearance of approximately 200 µm, with 50–100 µm of limbal clearance (van der Worp, 2010a; Caroline and Andre, 2011).

Although sodium fluorescein is often not used to fit miniscleral lenses by experienced contact lens practitioners, the sodium fluorescein fitting pattern for a miniscleral lens on an eye with keratoconus should demonstrate an even glow of fluorescein over the entire corneal surface and extending onto the sclera (Fig. 26.6). There must be no apical touch and limbal clearance is essential. Using white light and high magnification on the slit-lamp biomicroscope, the amount of corneal clearance can be determined by comparing the contact lens thickness, usually about 0.30 mm, with the tear layer thickness. When sodium fluorescein has been incorporated into the post-lens tear fluid, the tear layer will appear bright green (Fig. 26.7). For example, if the central tear layer thickness is approximately the same as the thickness of the miniscleral lens, then central corneal clearance is estimated to be about 300 µm (0.30 mm).

Alternatively, anterior-segment optical coherence tomography (OCT), which facilitates a highly precise, cross-sectional assessment of the interaction between the anterior corneal surface and contact lens in situ, can be used to quantify central and peripheral corneal clearances for miniscleral lens designs. Such an approach is particularly useful in keratoconus, where asymmetric clearance across the diameter of the lens is relatively common owing to the irregularity of the corneal profile. Later in this section there will be discussion regarding the maximal central clearance that should be adopted to minimize hypoxia-related corneal swelling with miniscleral lenses. OCT enables such quantifications to be performed relatively easily and reliably in a clinical setting. Anterior segment OCT can also be utilized to analyse the shape of the scleral curvature, which may be of assistance for determining the design of the scleral portion of the lens (Choi et al., 2014; Kauffman et al., 2014).

The utility of OCT for evaluating the fitting of miniscleral lenses is demonstrated by the OCT scans shown in Fig. 26.8. Fig. 26.8A shows the application of a miniscleral lens to vault a troublesome central corneal nebule on an eye with moderately advanced keratoconus. Fig. 26.8B highlights the ability to fit a miniscleral lens to an eye with marked corneal ectasia, which is associated with extreme central corneal thinning. Fig. 26.8C represents a close to optimal miniscleral lens fitting, with about 250 µm of central corneal clearance. Fig. 26.8D shows an OCT scan of the same lens and same eye as in Fig. 26.8C; however, the central corneal clearance is now significantly reduced owing to marked progression of the keratoconus over an 18-month period. Fig. 26.8E shows a poorly fitting miniscleral lens with pronounced apical bearing; this picture highlights a potential drawback of these larger-diameter rigid lens designs. This patient was originally prescribed an optimally fitted miniscleral lens that showed sufficient corneal apical clearance. The resultant harsh apical bearing is the consequence of significant progression of the keratoconus. However, this patient was unaware of any change to the eye (perhaps somewhat surprisingly) as the lens still felt comfortable and was delivering an acceptable level of visual acuity.

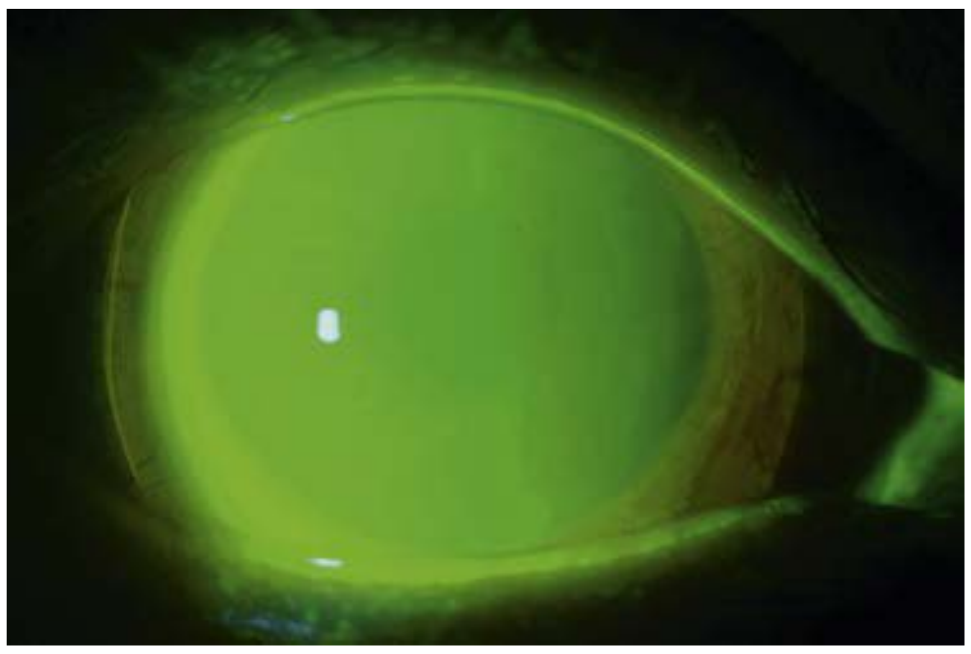
Fig. 26.6 A miniscleral contact lens on an eye with keratoconus. An en face sodium fluorescein photograph of a 16.50 mm miniscleral contact lens in situ showing complete vaulting of the lens over the corneal apex and limbus. (Courtesy of John Mountford.)

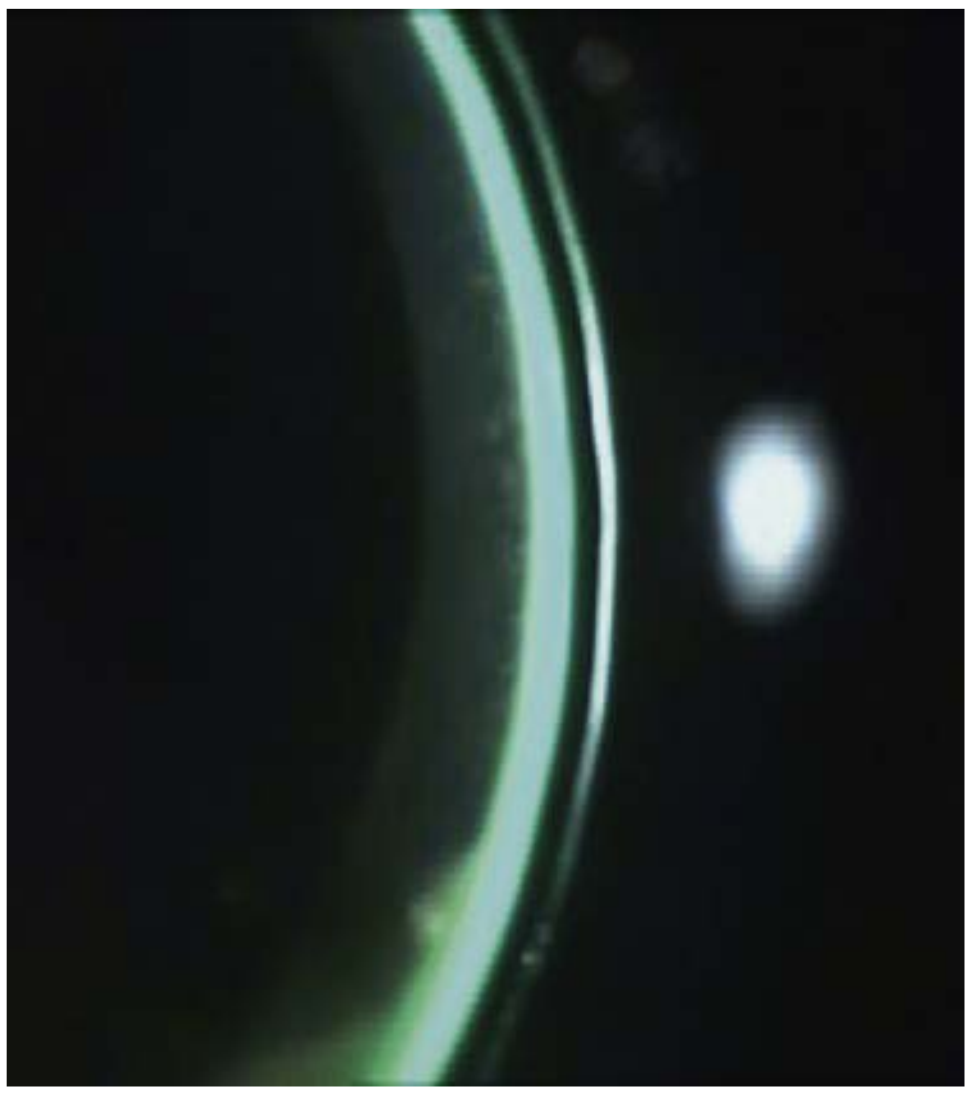
Fig. 26.7 Photograph showing the clearance of a miniscleral contact lens on an eye with keratoconus in cross-section. This photograph of an optical section shows how the apical clearance of a miniscleral contact lens on an eye with keratoconus can be determined by comparing the thickness of the contact lens (black) with the thickness of the tear layer (bright-green colour due to the instillation of sodium fluorescein). (Courtesy of John Mountford.)

Miniscleral lenses can be specified either by the radii of curvature of the central base curve and peripheral curves, or by the lens sagittal depth. The former allows the practitioner to specify the radius for any particular curve and facilitates easier power calculations as the base curve is adjusted; the latter is useful as the sagittal depth can be easily linked to the required corneal vault (Watanabe, 2013). Whereas the central corneal surface

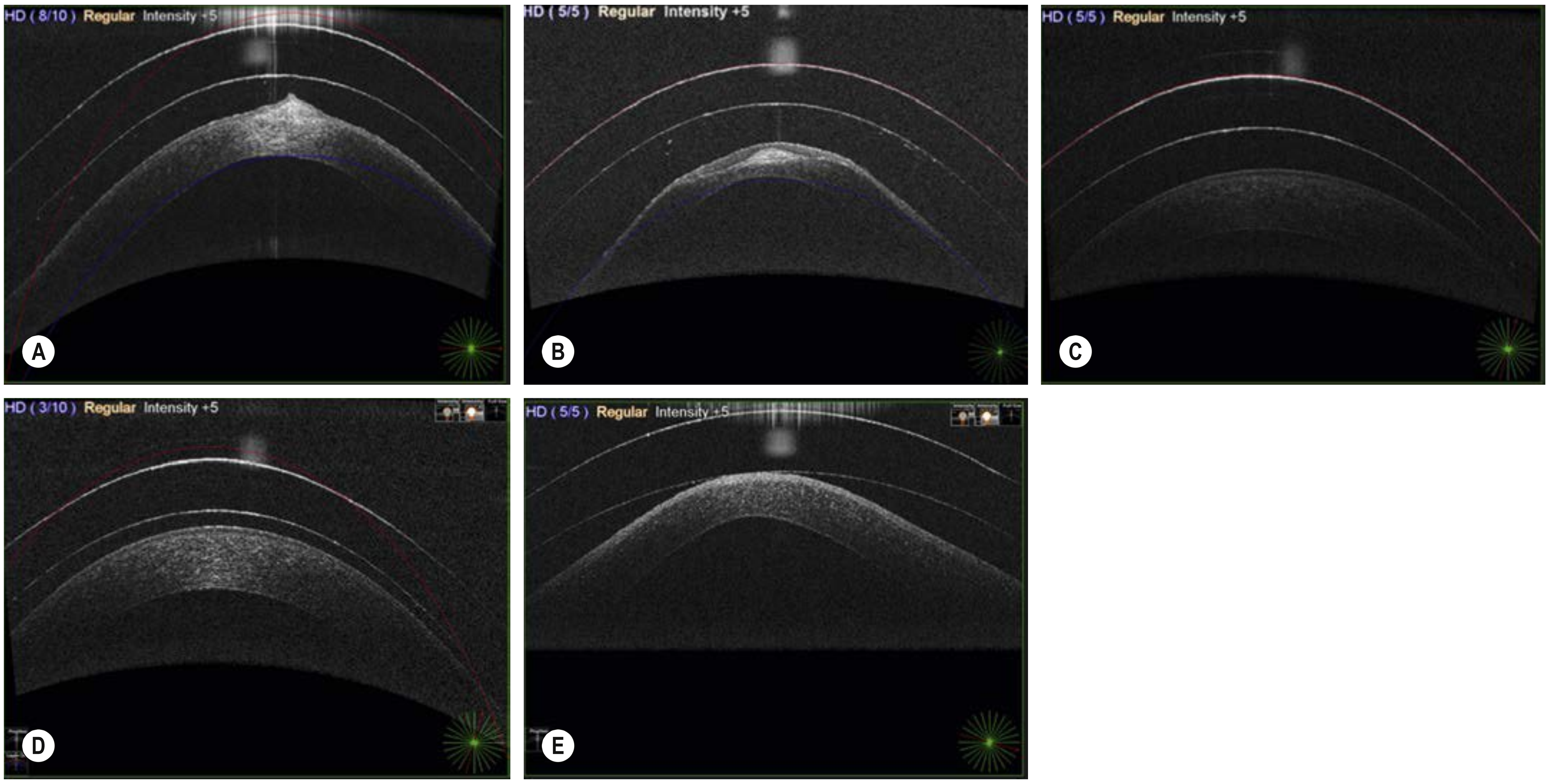
HD (8/10) Regular Intensity +5
A
HD (5/5) Regular Intensity +5
B
HD (5/5) Regular Intensity +5
C
HD (3/10) Regular Intensity +5
D
HD (5/5) Regular Intensity +5
E

Fig. 26.8 Anterior segment optical coherence tomography (OCT) for contact lens fitting in keratoconus: 8.0 mm scans of miniscleral lens on (A) an eye with moderately advanced keratoconus and a prominent corneal nebule; (B) an eye with highly advanced keratoconus and pronounced corneal ectasia; (C) an eye with moderate keratoconus showing about 250 µm of central corneal clearance; (D) the same eye as in part (C) (and the same miniscleral lens) after an 18-month time period; (E) an eye with relatively advanced keratoconus and a poorly fitting miniscleral lens, with apical corneal bearing.

over a 10 mm chord is curved, and appropriately described in terms of radii of curvature, beyond this central region the peripheral cornea, limbus and sclera generally form a straight line and are therefore more accurately described as a tangent angle (van der Worp, 2010a; Kojima et al., 2012). As a consequence, many miniscleral lens designs utilize adjustable tangent angles to provide limbal vault and tangential scleral landing. Other miniscleral designs have traditional radii of curvature that can be manipulated to optimize the fitting (Watanabe, 2013).

Miniscleral lenses are available in front-surface toric forms, to correct residual astigmatism, and can incorporate toric peripheral curves if the sclera has significant toricity. As miniscleral lenses vault the cornea, a toric central (base) curve is typically not required (Bierwerth and Edrington, 2012). Miniscleral lenses can also be manufactured with quadrant-specific peripheral designs (Watanabe, 2013), to assist with minimizing on-eye torsional effects that can arise from the sclera being increasingly more non-rotationally symmetric with increasing distance from the limbus (van der Worp, 2010a). A peripheral notch can also be incorporated to aid with avoiding lens interaction with conjunctival obstacles, such as pingueculae and post-trabeculectomy filtering blebs (DeNaeyer, 2014).

Accurately determining the BVP of a miniscleral lens requires care. With corneal rigid lenses, the post-lens tear layer is sufficiently thin that the approximation of thin lens optics can be applied when calculating the tear lens power. Thin lens theory does not apply for miniscleral lenses owing to the markedly thicker tear reservoir that is created by vaulting the cornea (Chan and Jackson, 2014). If thin lens theory is inappropriately applied to miniscleral lens BVP calculations, the power of a positive tear lens will generally be underestimated and the power of a negative tear lens will be overestimated (Chan and Jackson, 2014). It is also important to ensure that the miniscleral lens has fully settled onto the eye before performing an overrefraction, as the overrefraction will vary if the effective sagittal depth of the lens is changing during the period of on-eye lens settling.

Concern has been raised in relation to whether the oxygen transmissibility (Dk/t) through a miniscleral lens reaches the level necessary to avoid hypoxic corneal stress during daily wear (Michaud et al., 2012). The oxygen transmissibility through a miniscleral lens alone, when manufactured from a highly oxygen permeable material (see Chapter 11) such as Boston XO (Dk = 100 Barrer) would intuitively seem adequate (Weissman, 2006). However, it has been shown that in most cases the combination of the miniscleral lens and the thick underlying tear reservoir does not provide sufficient oxygen to avoid corneal hypoxia (Michaud et al., 2012), based on the Holden–Mertz criterion for the central cornea (Holden and Mertz, 1984) and the Harvitt and Bonanno standard for the limbal area (Harvitt and Bonanno, 1999). Chronic corneal hypoxia may lead to problems such as corneal neovascularization and/or a loss of corneal transparency (see Chapter 40). Furthermore, reduced oxygen supply at the corneal periphery can lead to serious complications, including limbal stem cell deficiency (Dua and Azuara-Blanco, 2000). Findings from a recent study indicate that miniscleral lenses may subtly influence corneal shape and power but do not induce clinically significant corneal oedema during short-term wear (Vincent et al., 2014). Other researchers recommend that miniscleral lens clearance should not exceed 200 µm if hypoxia-induced corneal swelling is to be avoided (Michaud et al., 2012). As previously discussed, limbal compression is a major stimulus for angiogenesis and so inadequate lens clearance at the periphery of the cornea and limbus is also not acceptable.

Scleral Lenses

As discussed in Chapter 21, scleral lenses can be fitted either from preformed sets or by impression moulding. Traditionally, impression scleral lenses have be made only in polymethyl methacrylate (PMMA), as gas-permeable materials are not thermoplastic, although it is sometimes possible for an optimally fitting PMMA lens to be duplicated in a gas-permeable material. In the 1980s, gas-permeable preformed scleral lenses were introduced. Although the use of these lenses in clinical practice has remained relatively infrequent, scleral lens pioneers, such as Ezekiel (1983) and Pullum (1997), have demonstrated the relative value of this modality for keratoconus patients. In addition to the obvious advantage of using a gas-permeable lens material, preformed lenses also have a number of advantages over impression scleral lenses, including an ability to specify lens parameters accurately and for fittings to be undertaken with diagnostic lenses having known specifications.

The criteria for a well-fitting scleral lens are similar to those outlined for a miniscleral lens. A scleral lens should clear the corneal apex after lens settling (Caroline and Andre, 2012) and not rest on the limbus; the scleral fitting should not be so tight as to cause conjunctival vessel blanching. As for minisclerals, scleral lenses can be produced in front-surface toric forms to correct residual astigmatism and/or with peripheral toricity if the sclera is highly toric (Bierwerth and Edrington, 2012). Quadrant-specific peripheral designs are also available (Watanabe, 2013). Although still currently limited to the research domain and not yet directly applicable to managing patients in clinical practice, customized aberration-controlled scleral lenses (Sabesan et al., 2013; Marsack et al., 2014) show promise as a potential future vision-correction platform for keratoconus. A range of factors will need to be overcome for the custom correction of highly aberrated eyes to achieve clinical translation. Such factors include the complexity of fitting (and the need for highly repeatable centration), the current cost of the devices (to patient and practitioner) and longer-duration studies to assess real-world effects on visual performance.

Scleral lenses can be manufactured with or without fenestrations. Fenestrations were used with impression scleral lenses to promote the exchange of freshly oxygenated tears; however, with preformed gas permeable scleral lenses fenestrations are not critical for oxygen delivery (van der Worp, 2010a) and there is conjecture as to the degree to which fenestrations aid oxygen flow to the cornea. The fitting philosophies of fenestrated and non-fenestrated scleral lenses are different, with the clearance in fenestrated lenses (about 100 μm) being less than that of non-fenestrated lenses (approximately 200 μm) (van der Worp, 2010a). (Please refer to Chapter 21 for a more detailed discussion on the fitting principles of scleral lenses.)

With regard to the oxygen transmissibility through scleral lenses, the same principles apply as previously discussed for miniscleral lenses, especially with non-fenestrated lenses; again, use of a highly oxygen-permeable material is critical, and attention must be paid to the maximum central lens thickness and the clearance under the lens so as to avoid corneal hypoxia (Michaud et al., 2012).

Piggyback Lens Systems

Piggyback systems consist of a soft contact lens, usually a disposable silicone hydrogel lens, worn beneath a rigid lens, generally a corneal or corneo-scleral lens (Lindsay et al., 2013). Changing to a piggyback system when rigid lenses have been previously worn alone may require a minor modification to the rigid lens parameters; this is usually an increase (flattening) of the BOZR so as to achieve an optimal fitting (Larson and Edrington, 2010).

Practitioners need to be aware that the effective power for a soft contact lens worn under a rigid lens in a piggyback system will be only approximately 20% of the specified power (Woo and Weissman, 2011). For example, if a piggyback system is created by placing a soft lens with a BVP of −0.50 D under a rigid lens, then the contribution of the soft lens to the overall power of the piggyback system will be negligible. In other words, if a patient is corrected appropriately with just their rigid lens, then changing them to a piggyback system by incorporation of a soft lens with BVP of −0.50 D will not necessitate a change to the BVP of their existing rigid lens. It has been suggested that using a soft lens with a relatively high positive power (i.e. greater than +4.00 D) in a piggyback system will help to improve the centration of a rigid lens on a keratoconic cornea with a markedly inferior sagging cone (Larson and Edrington, 2010). In such cases, the relative contribution of the soft lens BVP to the soft–rigid lens system should be considered. Other authors recommend the use of negative-powered soft lenses in piggyback fitting, which can reduce the rigid lens BVP without significantly impacting visual acuity (Romero-Jimenez et al., 2015).

Piggyback contact lens systems are usually adopted when fitting with a rigid lens alone may lead to corneal insult, owing to underlying ocular surface disease, or for a highly irregular cornea. The soft contact lens is considered to assist with protecting the corneal surface from rigid lens bearing, thereby minimizing this potential complication of rigid lens wear and also enhancing lens comfort (Szczotka and Lindsay, 2003). Two clinical examples where the use of a piggyback contact lens system may be indicated include nebular-like scarring at the corneal apex and chronic 3 and 9 o'clock corneal staining.

For patients with significant residual astigmatism, piggyback lens systems can have the additional advantage of incorporating the residual astigmatism correction into a soft toric contact lens. This option enables the rigid lens to remain spherical and eliminates the need to incorporate rigid lens stabilization features, which may make the lens less comfortable (Lindsay et al., 2013).

Concern has been expressed over whether the oxygen transmissibility through a piggyback contact lens system can reach the level required to avoid hypoxic stress to the cornea during daily wear (Holden and Mertz, 1984). Weissman and Ye (2006) have calculated that in open-eye conditions, the oxygen supply to the cornea is sufficient when both rigid and soft lenses have been manufactured from materials that have an oxygen permeability (Dk) greater than 60 Barrer.

HYBRID LENSES

Hybrid contact lenses, which were first introduced into clinical practice over 30 years ago, consist of a rigid central zone and a soft peripheral 'skirt' (Fig. 26.9A). A major attraction of this modality is the potential to combine the preferred fitting properties of rigid and soft contact lenses (i.e. the visual performance of a rigid lens with a comfort and stability profile similar to that of a soft lens) (Downie, 2014a).

Historically, the main hybrid lens option for keratoconus was the SoftPerm (CIBA Vision) lens. Although this design represented a major improvement on its predecessors, fitting success for keratoconus was limited by several factors, including a restricted range of parameters, limited durability

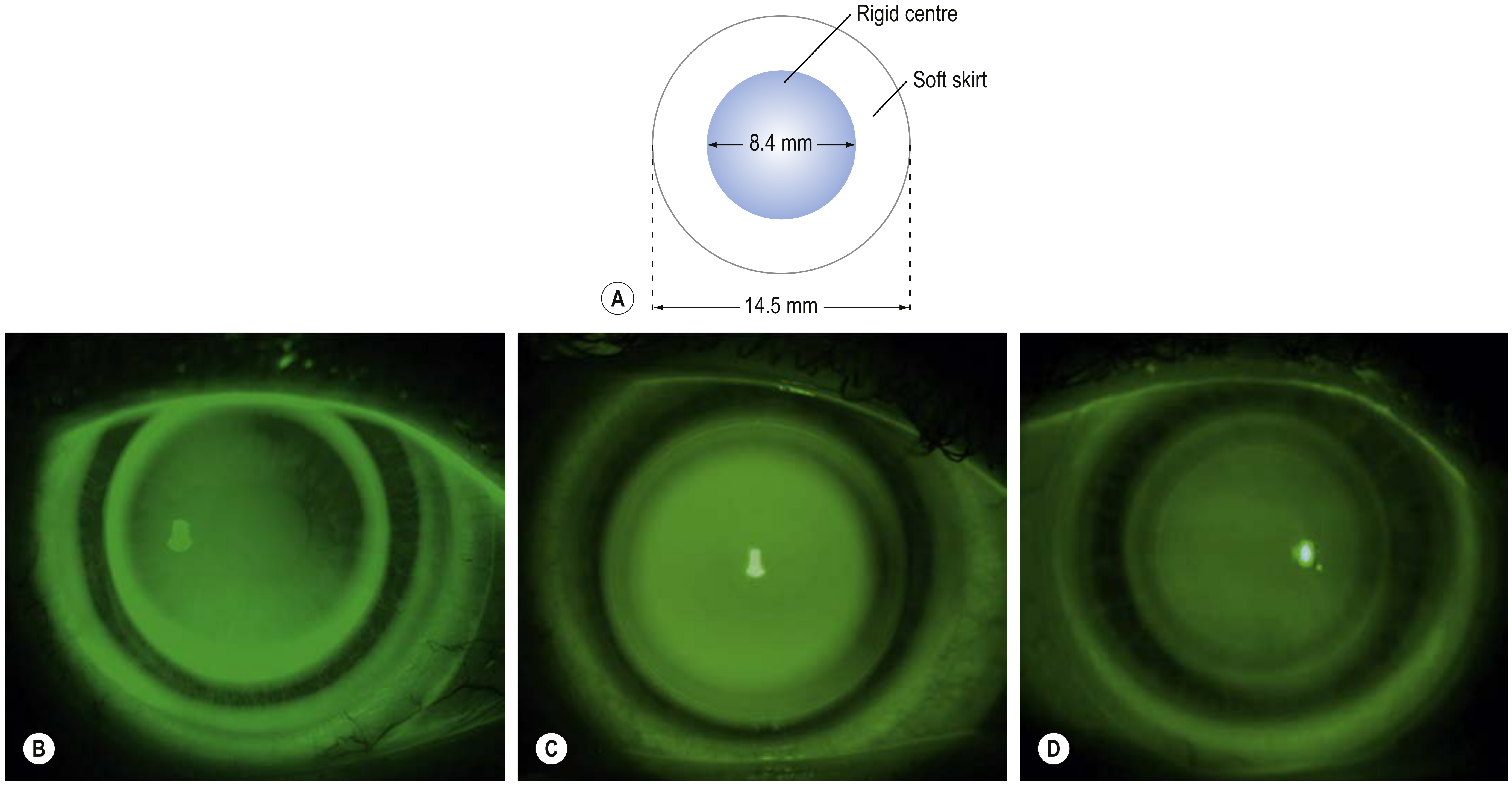

Fig. 26.9 Hybrid contact lens fitting in keratoconus. (A) The configuration of a SynergEyes hybrid contact lens, with a rigid lens centre being bonded to a soft skirt. Sodium fluorescein photographs of (B) SynergEyes KC, (C) SynergEyes ClearKone and (D) SynergEyes UltraHealth hybrid lenses in situ. (From Downie and Lindsay (2015) and used with permission from Clinical and Experimental Optometry.)

of the rigid–soft junction and suboptimal oxygen transmissibility. In a published retrospective case series of SoftPerm contact lens wearers, peripheral corneal neovascularization was reported in approximately one in four long-term SoftPerm lens wearers (Ozkurt et al., 2007). Today, SynergEyes (Carlsbad, CA, USA) are the leading manufacturer of hybrid contact lens designs. For keratoconus, SynergEyes hybrid lenses fall into two major categories, namely a base-curve-based design (KC) and vault-driven designs (ClearKone and UltraHealth).

A distinct fitting rationale applies to each of the SynergEyes lens designs. The KC design involves the specification of a rigid BOZR (in millimetres) and soft skirt curvature (effectively being the BPR). A well-fitted KC lens should demonstrate full apical clearance, with soft landing of the lens at the junction zone (Fig. 26.9B). For this design, steeper skirt curvatures promote an increase in the over-lens sagittal depth; this has the effect of imparting a relatively gentler landing at the junction zone compared with flatter skirt curves.

The ClearKone lens features a reverse geometry design and requires the determination of rigid lens vault, in µm, and skirt curvature. As with the KC lens, the aim is to avoid apical bearing. At the rigid–soft junction, an optimal ClearKone fitting involves a graded thinning of sodium fluorescein; the soft skirt should then land on the cornea, distal to the junction zone (Fig. 26.9C) (Downie, 2013).

The UltraHealth design requires the specification of similar parameters to the ClearKone (i.e. vault and skirt curvature). The fitting principles do, however, vary owing to the silicone hydrogel, rather than hydrogel, skirt and a distinct junction-zone design. UltraHealth lens fittings typically require relatively flatter skirt curvatures than do KC and ClearKone lenses, so as to minimize peripheral lens seal-off (personal communication, SynergEyes Inc.). An optimally fitted UltraHealth lens is shown in Fig. 26.9D.

Similar to rigid lenses, hybrid lens designs are traditionally fitted using diagnostic sets, although corneal-topography-derived data have been shown to be of value for predicting ClearKone lens parameters (Downie, 2013). High-molecular-weight sodium fluorescein should be used when fitting hybrid lenses incorporating a hydrogel soft skirt. Hybrid lenses are applied to the eye using the same method as for scleral lenses (see Chapter 21). In brief, this would typically involve filling the hybrid lens with a unit-dose or non-preserved saline solution, and then gently elevating the lens to approach the surface of the eye whilst the patient's face is oriented parallel to the floor. Care should be taken to minimize the loss of saline from within the hybrid lens during this process. The presence of an air pocket (bubble) under the rigid portion of the lens represents a lens application error, rather than being indicative of excessive lens vault. In these circumstances, the hybrid lens should be removed, refilled with solution and reapplied to the eye in order to accurately assess the quality of the fitting. It has been suggested that the thickness of the tear reservoir beneath the rigid portion of a hybrid lens should be less than 100 µm in order to deliver acceptable oxygen tensions at the corneal surface (Lee et al., 2015). Anterior segment OCT can be used to quantify accurately the amount of corneal clearance of a hybrid contact lens in situ; as the patient blinks, dynamic changes in clearance may also be observed.

At present, there is relatively limited literature relating to the clinical performance of hybrid contact lenses in patients with keratoconus. A chart review of 44 patients (61 eyes) with corneal ectasia who were fitted with SynergEyes KC lenses at the Cornea Service at Wills Eye Institute (USA) reported that close to 90% of patients were successfully fitted with this design (Abdalla et al., 2010). Unsuccessful fittings were, perhaps surprisingly, primarily due to inadequate lens comfort (Abdalla et al., 2010). Visual acuity outcomes with SynergEyes ClearKone and corneal rigid lenses have been reported to be similar in people with keratoconus; in this comparative case series, overall satisfaction and vision-related quality of life was relatively higher with the hybrid lens modality (Hashemi et al., 2014).

Monitoring Keratoconus Progression

Patients with keratoconus require careful monitoring for disease progression. The quantification of longitudinal changes to corneal curvature is necessary both for contact lens fitting (for the modification of lens parameters if required) and for potentially enabling timely referral for ophthalmologic assessment with regard to corneal collagen cross-linking (CXL). CXL, which induces photo-oxidative cross-linking of the corneal stroma, demonstrates significant promise for arresting the clinical progression of keratoconus (Hersh et al., 2011; O'Brart et al., 2011; Wittig-Silva et al., 2014). The procedure is undertaken with the intention of enhancing corneal biomechanical stability so as to attenuate disease progression (Spoerl et al., 1998). The need for spectacle and / or contact lens correction typically persists after CXL.

The relative risk of progressive keratoconus and acute corneal hydrops is strongly associated with a patient's age at diagnosis (Downie, 2014a). Keratoconus is one of the most common indications for childhood keratoplasty. The condition accounts for approximately one in five corneal grafts performed in children (Cowden, 1990; Patel et al., 2005). Diagnosis of keratoconus in a young patient is therefore essential for enabling an opportunity for CXL to be administered within the therapeutic window. Primary eyecare providers have an important role in screening for childhood corneal ectasia, particularly when risk factors may be present (e.g. family history of keratoconus, atopy, history of eye rubbing), to enable early diagnosis and appropriate management. There is a growing body of evidence that supports the safety and efficacy, in relation to corneal stabilization, of paediatric CXL (Caporossi et al., 2012; Chatzis and Hafezi, 2012; Soeters et al., 2014).

The long-term visual management of a child with keratoconus is also of major importance. The likelihood of more rapid progression in younger patients poses a higher risk of vision impairment, which can negatively impact upon learning and social interaction (Kankariya et al., 2013). Overall, the approach for contact lens correction in children with keratoconus is similar to that in adults, the primary goal being to improve visual acuity using a lens modality that is comfortable, practical and physiologically acceptable. Scleral lenses have been used to provide effective visual and ocular surface rehabilitation to children with corneal ectasia and comorbid ocular surface disease (Rathi et al., 2012).

It should be emphasized to patients in particular that, with appropriate care to facilitate functional vision, most people with keratoconus will not need to undergo a corneal transplant. At present, approximately one in ten people with keratoconus may eventually require a corneal graft (Cassidy et al., 2013); however, with the availability of CXL we would expect this incidence to decrease significantly over time. The key indications for ophthalmologic referral for an opinion with regard to suitability for keratoplasty include highly advanced corneal thinning or protrusion that precludes contact lens fitting by an experienced clinician, contact lens intolerance to well-fitted lenses, the presence of sight-impairing corneal scarring, and / or when there is a substantial risk of corneal perforation, albeit this is relatively unlikely in keratoconus.

Conclusion

Keratoconus is a clinically challenging, but extremely rewarding, area of contact lens practice. Given the variations in clinical phenotype that exist, there remains a need for practitioners to adopt an individualized, and often creative, approach to keratoconus management. Contemporary contact lens practice is fortunately supported by a diverse repertoire of lens modalities and materials, enabling most people with keratoconus to achieve successful, long-term visual outcomes. The availability of newer imaging technologies, such as anterior-segment OCT, are also redefining many of the methods currently used to assess corneal integrity and the corneal–lens relationship in vivo. Continued advances in lens technology are predicted to provide the foundation for further improvements in the contact lens care that can be provided to people with keratoconus.

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27

High Ametropia

JOSEPH T BARR

Introduction

Care for the highly ametropic patient is one of the most challenging and yet one of the most rewarding aspects of contact lens practice. The most common indications for this care are high myopia, high corneal toricity and thus high astigmatism, and adult and paediatric aphakia. This is especially true in cases of unilateral high ametropia, resulting in high anisometropia and possibly aniseikonia. These cases are challenging owing to the high lens centre thickness of plus lenses and high edge thickness for minus lenses, the need for lenticularization, and centre-of-mass difficulties, as well as the fact that these eyes often have pathological changes. These pathological changes include degenerative myopia, cataract surgery and increased risk of retinal detachment.

Highly hyperopic and aphakic patients benefit from decreased need for head turning, better peripheral vision, and elimination of blind areas in their field of view with spectacles ('jack-in-the-box'), but they have less magnification in contact lens wear as compared with spectacles. These patients also have a larger image size with spectacles but prefer contact lenses because of the field-of-vision benefits. Highly myopic patients benefit from the increased magnification (less minification) compared with spectacles (see Chapter 3). These high myopes have significantly improved visual acuity as a result. The highly astigmatic patient benefits from contact lenses as compared with spectacles, primarily as a result of the elimination of aniseikonia.

All of these patients benefit from improved cosmesis compared with thick, unsightly spectacle lenses. This factor, coupled with a visual performance overall that is superior to that with spectacles, generally means that the highly ametropic patient will be strongly motivated to persevere during the initial adaptation phase of lens wear (Astin, 1999).

Lens Materials for High Ametropia

Just like the thick spectacles high ametropes seek to avoid, their contact lenses are also likely to be relatively thick. This produces challenges for lens design and oxygen transmission to the cornea. High ametropia usually requires the use of custom-made lenses to produce the power and base curves necessary. The practitioner may choose from any of the following material types:

- high-water-content soft lenses (may be used with close monitoring)
- silicone elastomer lenses (often wet poorly, can be hard to remove)
- silicone hydrogel lenses (high transmissibility)
- rigid lenses (give the best tear flow).

ELASTOMER

The use of silicone elastomer lenses has not become widespread; however, they do have a place in fitting aphakic and other high-plus patients. Silicone lenses are typically 11.3–12.5 mm in diameter and are fitted with a base curve near to or only slightly flatter than K.

SILICONE HYDROGEL

Silicone hydrogel lenses have been available for many years for ametropia between +8.00 and −20.00 D. The vast majority of lens wearers are potentially able to benefit from the increased oxygen that they provide.

Developing a silicone hydrogel material for the specialty contact lens industry has not been a straightforward proposition. First-generation lens materials were all developed for cast moulding and many required surface treatment. There were various obstacles to overcome before a silicone hydrogel material was produced in a button form that could be processed into a contact lens (Tapper, 2006):

- The lathing of silicone hydrogel materials is made difficult by the inclusion of a silicone component, as such materials are relatively soft. The lathe turning of these softer materials to produce lenses with acceptable optical quality requires the highest-performing machine platforms currently available.
- Commercial constraints: companies have invested heavily in developing these materials and considerable knowledge has been derived from these activities, with any significant breakthroughs being carefully protected by the enforcement of patents.
- Raw material costs are high.

There are currently four silicone hydrogel lenses that can be made in custom designs. Their properties are shown in Table 27.1. All the lenses are manufactured by lathing and are recommended for daily wear only. Although the transmissibility of these materials is not as high as that of other available silicone hydrogels, they still allow the criteria of Holden and Mertz (1984) for daily wear to be fulfilled in a wider range of designs than can currently be achieved with conventional hydrogels (Young and Tapper, 2008).

These lenses should therefore provide relief from the hypoxia that has been inherent with low-Dk soft lenses and allow better comfort and planned replacement of lenses compared with rigid materials. Silicone hydrogel high-plus lenses are fitted like soft contact lenses.

Kwok et al. (2012) have noted that correcting the foveal refractive error in high myopia with standard spherical soft contact lenses can result in significant absolute myopic defocus in the

TABLE 27.1 Silicone Hydrogels for Lathe Cutting and Custom Fitting

Brand Name	Manufacturer	Material Name	Water Content (%)	Oxygen Permeability (Barrers)	Material Modulus (MPa)
Definitive	Contamac	Filcon V3	50	50	0.60
		Filcon V4	65	62	0.75
		Filcon V5	74	60	0.35
LSH Lagado	Menicon	LSH Lagado	49	49	0.80

All data are manufacturer reported.
For a summary of aphakic and specialty design custom hydrogel contact lenses, see www.clspectrum.com/class.

peripheral retina. If peripheral refraction does indeed influence myopia progression (see Chapter 33), then the induced peripheral myopic defocus that occurs in contact lens correction of high myopia may be beneficial in reducing myopia progression.

Principles of High-power Lens Design

The main aim when designing high-powered lenses is to reduce the mid-peripheral thickness of minus lenses, or the centre thickness of plus lenses, and at the same time to ensure that the optic zone is of sufficient diameter and is centred on the pupil. These principles apply equally to soft and rigid lenses. It will also be necessary to correct for back vertex distance in both the flat and steep meridians to determine the lens power (Appendix C).

HIGH-PLUS

High-plus rigid lenses, unless they are of very small diameter (8.5 mm or less) and of steep fit, must be made in regular (parallel) carrier form or minus (edge thicker than junction) carrier form; lenticular lenses are thinner, have less mass and centre better than non-lenticular designs (Fig. 27.1). Typically these lenses are 9.0–10.5 mm in diameter. Regular carrier designs are better for lens positioning between the eyelids. Minus carrier lenses are better for lid attachment fitting (Fig. 27.2). The smaller the front optic zone diameter, the thinner is the lens. The front optic zone diameter may be equal to, larger than or smaller than the back optic zone diameter. Typically the front optic zone diameter is 7.0–8.0 mm in diameter, and the back optic zone is designed as needed for fitting. Junction thickness for lenticular rigid plus lenses should be thin enough to minimize lens thickness, but thick enough to allow adequate lens strength (about 0.15 mm). Regular carrier unfinished edge thickness is typically 0.10–0.12 mm and minus carrier unfinished edge thickness is typically approximately 0.2 mm. Lenticular (front peripheral) radii range from approximately 0.2 mm flatter than the posterior secondary curve (regular carrier) to 3.0 mm flatter than the posterior secondary curve (minus carrier) (Polse, 1988).

Even with a lenticulated front surface, the centre of gravity of a rigid lens is relatively anterior and may cause the lens to drop excessively. This can sometimes be solved by fitting a corneoscleral or mini-scleral design. Not only is centration improved, but also there is less movement and handling may be easier.

APHAKIA

Fortunately, adult aphakia is now rare owing to the high success rate of intraocular lenses. However, in some cases such as aniridia, chronic uveitis and glaucoma, contact lenses may be indicated.

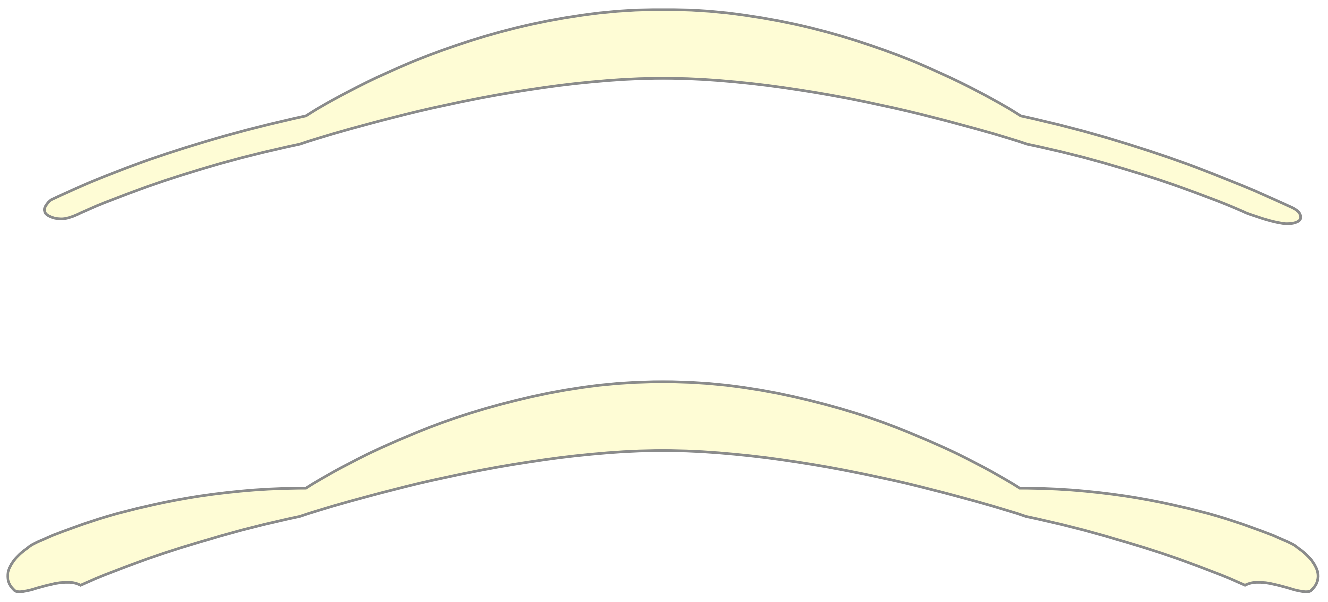

Fig. 27.1 Lenticular lens designs. (Top) regular (parallel) carrier. (Bottom) minus carrier.

If extended wear is desired to minimize frequent lens handling, lenses of maximum oxygen transmissibility are recommended. These patients may, with proper monitoring, wear their lenses for a month at a time, if the benefits outweigh the risks. High-water-content soft contact lenses may be preferred for comfort over rigid ones, particularly in monocular aphakia, and should be selected to maximize oxygen transmissibility for extended wear. Low-water-content lenses are not used, because the risk of hypoxic problems is high (interestingly, the aphakic eye may swell less than an unoperated eye; Holden et al., 1982). Handling typically will be difficult in bilateral aphakic patients owing to poor uncorrected vision and reduced manual dexterity in the elderly. Some aphakes may prefer to handle soft lenses because of their large size, and some may prefer rigid lenses because of their stiffness.

Residual astigmatism and reading additions for near work can be corrected in spectacles to be worn over the contact lenses.

Patients with conjunctival filtering blebs should be monitored closely and contact lenses should not impinge on these blebs excessively. Preferably, topical ocular medication is instilled before and after lens wear, and only under close supervision during contact lens wear.

Lambert et al. (2014) compared the visual outcomes of patients optically corrected with contact lenses with those of intraocular lenses following unilateral cataract surgery during early infancy. They found no significant difference between the median visual acuity of operated eyes in children who underwent primary intraocular lens implantation and those left aphakic. However, there were significantly more adverse events and additional intraoperative procedures in the intraocular lens group. Lambert et al. (2014) recommend that, when operating on an infant younger than 7 months of age with a unilateral cataract, the eye should be left aphakic and corrected with a contact lens. Primary intraocular lens implantation should be reserved for those infants where, in the opinion of the surgeon, the cost

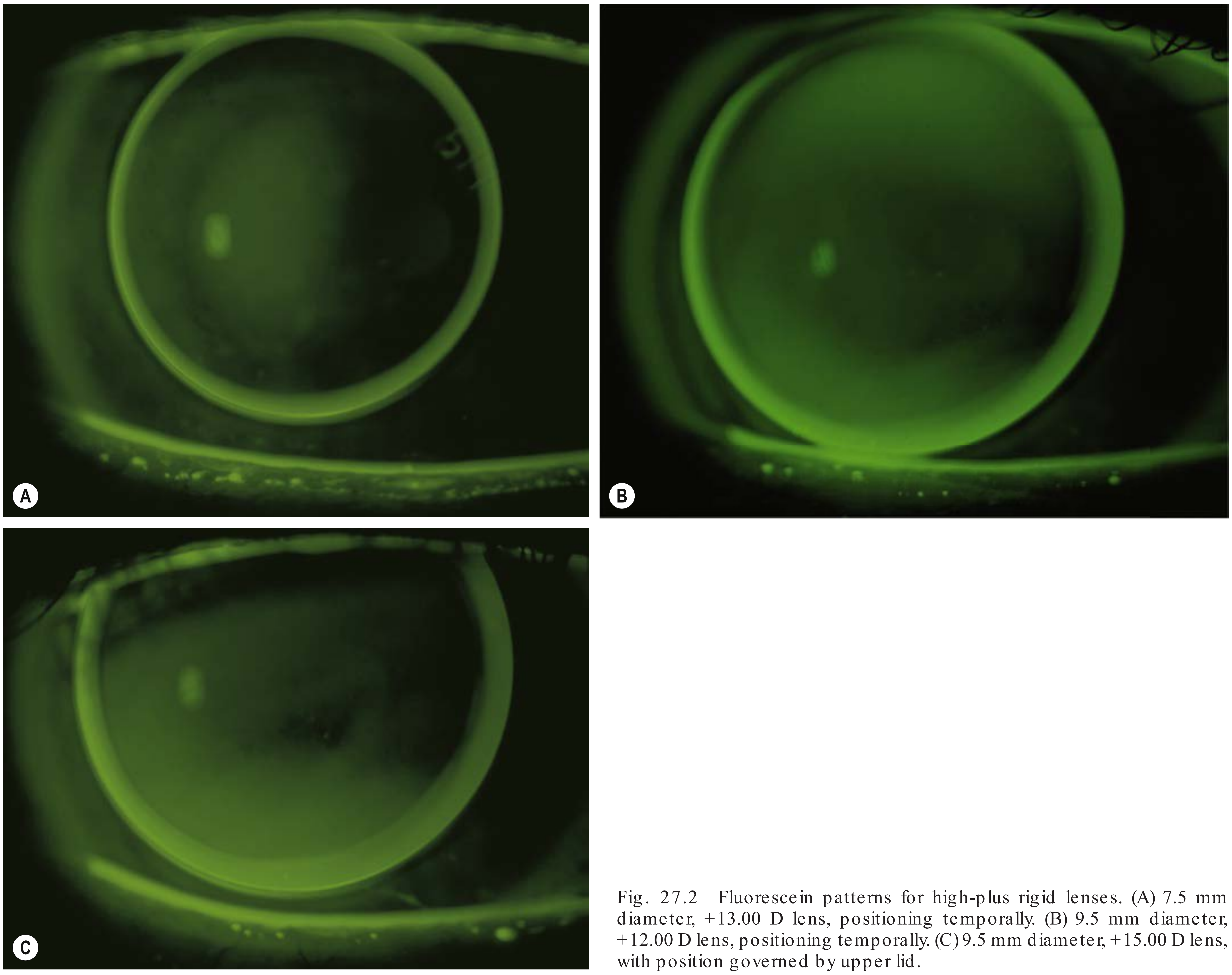

Fig. 27.2 Fluorescein patterns for high-plus rigid lenses. (A) 7.5 mm diameter, +13.00 D lens, positioning temporally. (B) 9.5 mm diameter, +12.00 D lens, positioning temporally. (C) 9.5 mm diameter, +15.00 D lens, with position governed by upper lid.

and handling of a contact lens would be so burdensome as to result in significant periods of uncorrected aphakia. The correction of paediatric aphakia is dealt with in detail in Chapter 28.

HIGH-MINUS

A rigid contact lens of −10.00 D would have an unfinished edge thickness of approximately 0.32–0.35 mm if the diameter is 8.8–9.6 mm. Because unfinished edge thickness for best comfort and lens stability should be approximately 0.10 mm, lenticularization of high-minus lenses is very important. This can be performed by CN bevelling, grinding the excess edge thickness by hand in a diamond-impregnated cone-shaped tool, and then polishing this area. Preferably, the laboratory will use a computer numerical-controlled lathe to cut a steeper anterior lenticular radius to obtain the proper edge thickness.

Typical front optic zone diameters range from 7.2 mm (8.8 mm lens diameter) to 7.8 mm (9.6 mm lens diameter) and are about 0.2 mm larger than the back optic zone. The lenticular radius may be cut flatter for a smaller front optic zone or steeper for a larger front optic zone. The latter design will result in higher mid-peripheral thickness. The higher the power – with the same front optic zone – the thicker will be this mid-peripheral area (Fig. 27.3). This may complicate the fit and cause discomfort if the lens does not attach to the upper eyelid. Greater mid-peripheral thickness may also cause a high-riding lens to ride even higher. Mid-peripheral thickness can be reduced with proper polishing or advanced multicurve computer-controlled anterior-surface lathing (Fig. 27.4) (Moore and Mandell, 1989).

HIGH ASTIGMATISM

High astigmatism is typically caused by high corneal toricity. Custom soft toric contact lenses are available in high powers. Of course, the higher the cylinder power in the lens, the more a given degree of unwanted lens rotation will cause blur. If rigid lenses are not desirable, for example in dusty environments, soft toric lenses may be preferred. Oblique astigmatism is difficult to manage with soft toric contact lenses. The higher the corneal toricity, the better is the orientation stability with

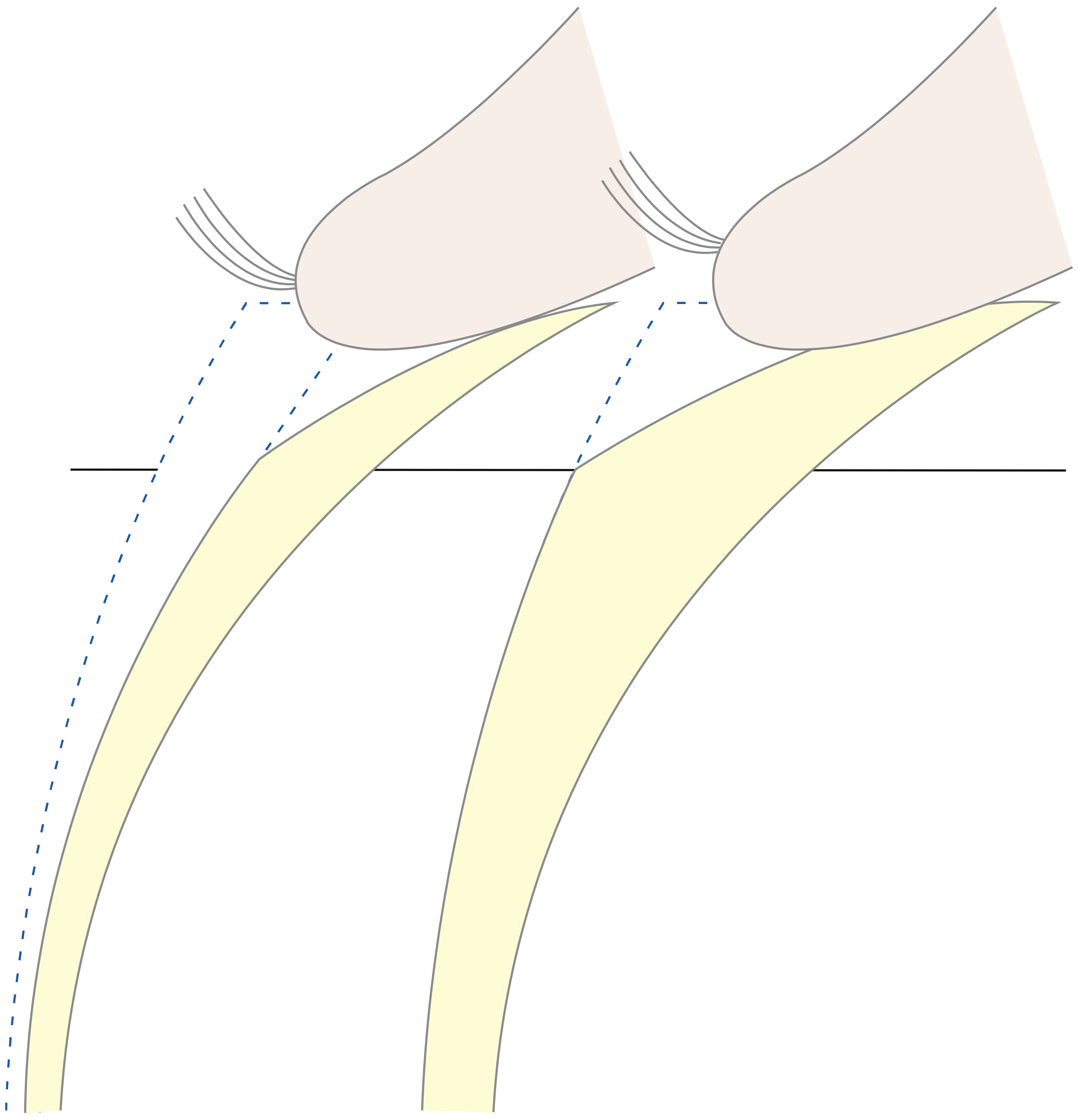

Fig. 27.3 Low-minus-power lens (left) with same front optic zone diameter as the high-minus-power lens (right). Junction thickness (horizontal straight line) is greater for the high-minus-power lens.

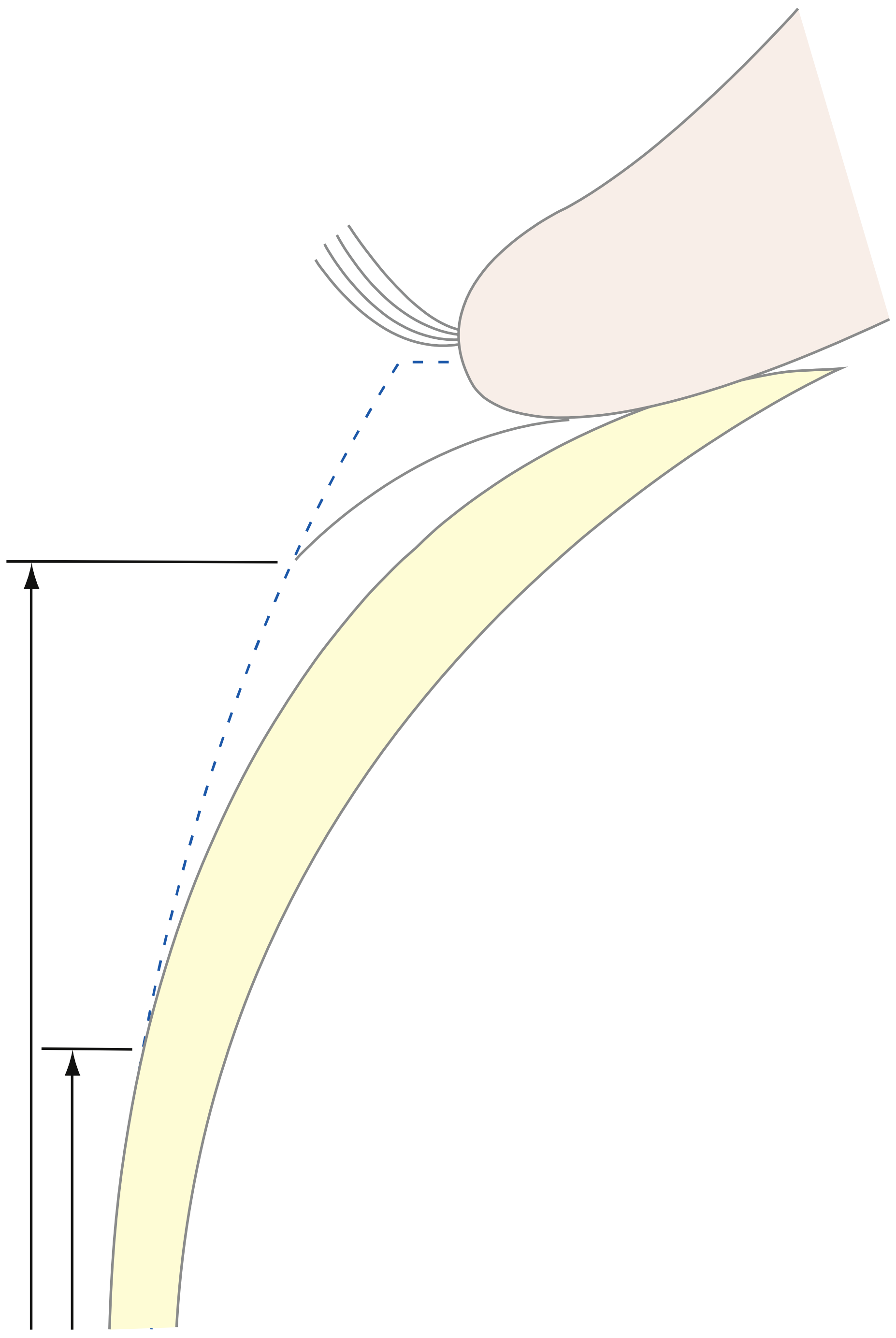

Fig. 27.4 Optimized high-minus-power lens design.

rigid bitoric lenses. Against-the-rule toric corneas are difficult to fit with spherical rigid lenses owing to poor lateral lens centration, unlike with-the-rule corneas where the upper eyelid can help position the lens properly. Bitoric rigid lenses may be fitted with toric base curves that are slightly less toric than the corneal toricity. The spherical power effect bitoric lens (where the base curve toricity in dioptres equals power difference in dioptres) may rotate somewhat off-axis without causing residual astigmatism. Highly toric rigid lens designs – up to 11.00 D of base curve toricity and cylinder power – are possible.

Another option occasionally used for irregular astigmatism, such as keratoconus, is a very thick soft contact lens. Such a lens will minimize the irregular astigmatism and correct most of the spherical component of the refractive error; the residual refractive error is corrected with spectacles. The drawback of this approach is such lenses will generally have very low oxygen transmissibility.

Fitting Challenges

Blinking can result in excessive movement of high-plus rigid contact lenses, although more stability and less decentration can be achieved if lenticular designs are used. Soft lenses will generally be more stable in the eye.

Both high-plus and high-minus rigid lenses may tend to drop on the cornea to a low-riding position. This will result in peripheral corneal staining, as well as discomfort and possibly poor vision. Both lens types have high mass compared with low-power lenses, with the high-minus lens actually having more mass than a plus lens of equivalent power and diameter, owing to the increased thickness around the lens periphery. This is complicated by the centre-of-mass differences. The minus lens has a centre of mass further behind the lens posterior surface (Carney et al., 1987), which causes better centration forces for the minus lens and poorer fitting (dropping) of the plus lens. Lenticularization of both designs will assist in fitting and a minus carrier design on a plus lens can help the upper lid to hold the lens up, much like a high-minus lens that is held in place by the upper eyelid.

Lens-positioning problems may be solved with 'piggyback' fitting. Most commonly used in keratoconus, this system employs a soft spherical lens (typically a disposable lens in low-minus power) with a rigid lens fitting over it. A special soft lens with a cut-out central portion (depression in the front surface) is available. A rigid lens that is 0.5 mm smaller than the cut-out portion of the soft lens is fitted over this soft lens. Scleral lenses, manufactured from high-oxygen-permeability rigid materials, are always an option for the high ametrope. The lens may be designed to incorporate a negative power tear layer to assist with the myopic correction (see Chapter 21).

Of course, for high ametropia, contact lens power may only partially compensate for the ametropia and the residual refractive error may be corrected with spectacles – especially residual astigmatism and presbyopic correction.

Low Vision

One unique and rarely used contact lens application is the Galilean telescope system. For example a −30.00 D contact lens can be used in conjunction with a +20.00 D spectacle lens at a 17 mm vertex distance to obtain 1.5× magnification. With a 40 mm spectacle eye size, field of view is limited to 68° with this system (Mandell, 1988).

Conclusion

Best care for highly ametropic patients demands that the practitioner understand:

- the unique examination necessities, especially for paediatric patients
- the lens design options, especially with lenticular forms
- the lens material options
- the interaction between lens design and fitting of high-powered lenses
- the magnification properties of high-power lenses
- the contact lens treatment options.

By working in collaboration with a custom lens laboratory, practitioners should be able to find an appropriate contact lens solution for most cases of high ametropia.

Access the complete references list online at http://www.expertconsult.com.

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28

Babies and Children

CINDY TROMANS | HELEN WILSON

Introduction

The contact lens practitioner is a key member of a multidisciplinary team involving paediatric ophthalmologists, optometrists and orthoptists concerned with ocular health and visual development of the child. Fitting infants and children with contact lenses is a challenging yet rewarding area of clinical contact lens practice. Contact lenses play an important role in the correction of complex refractive errors in infants and young children (Davies, 1998). They can also be used in the management of binocular vision anomalies, for therapeutic and prosthetic purposes, and for elective wear in older children and teenagers.

Indications

APHAKIA

One of the most common indicators for contact lens fitting in infants is aphakia resulting from the surgical removal of the crystalline lens because of congenital cataract. The incidence of congenital cataract (Fig. 28.1) is reported as being 2.1 per 10 000 live births and 7.7 per 10 000 at 4 years of age (Taylor, 1998); of these cases, around 40% and 50%, respectively have unilateral cataracts. Aphakia can also result from lens subluxation, as seen in Marfan's syndrome, or ectopia lentis. Trauma to the eye may result in the immediate loss of the crystalline lens or subsequent development of traumatic cataract, which may require surgical intervention.

Refractive management of bilateral aphakia can be achieved with spectacles (Fig. 28.2). However, the drawbacks of aphakic spectacles include the weight of the lenses and difficulty in achieving a good frame fit in babies and young infants. In addition, the maximum power of lenses is restricted, even in lenticulated form, to around +26.00 D.

Fig. 28.3 shows a 3-week-old bilateral aphake wearing high-water-content hydrogel contact lenses of around +35.00 D power.

In cases of unilateral cataract, contact lens correction is essential for managing the resultant anisometropia.

Surgery for congenital cataract is usually performed within the first 6 weeks of life to limit deprivation amblyopia, so it is vital to be aware of the rapid changes in the ocular dimensions that occur within the first few months of life. The average radius of curvature in a newborn is around 6.90 mm and this will flatten rapidly in the first 6 months of life (Inagaki, 1986). Axial length will increase rapidly from around 17.00 mm in neonates to 21.00 mm within the first 6 months of life and then more slowly during later infancy and childhood (Larsen, 1971). These changes cause a 'myopic shift', with the aphakic correction decreasing from +35.00 to +20.00 D in the first few years of life. However, eyes with congenital cataract can have associated disorders such as persistent hypoplastic primary vitreous and microphthalmos, which require steeper-radii lenses and powers in excess of +50.00 D.

Average fittings of a high-water-content hydrogel lens based upon age, corneal radius and diameter are shown in Table 28.1.

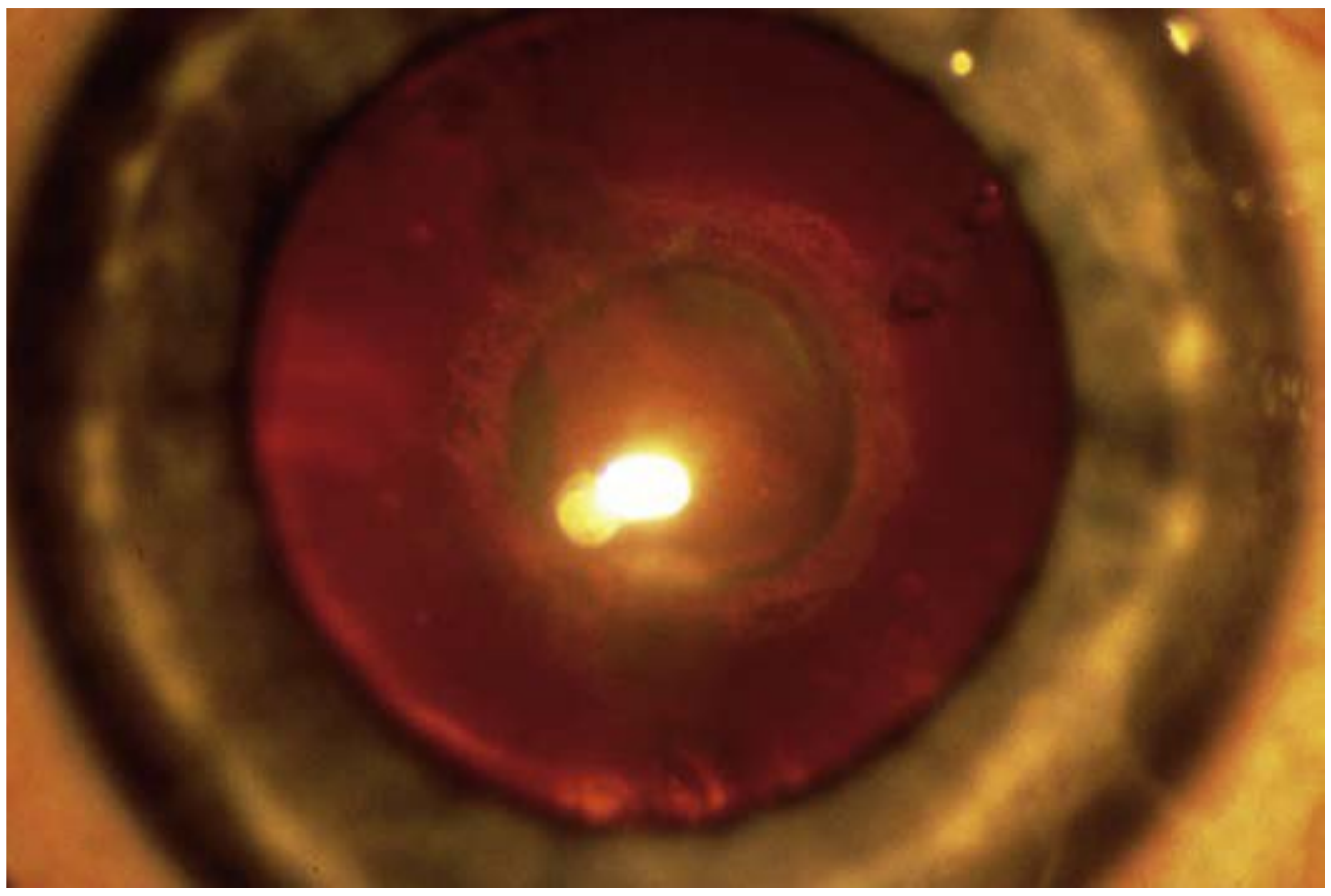

Fig. 28.1 Congenital cataract. (Courtesy of I. C. Lloyd.)

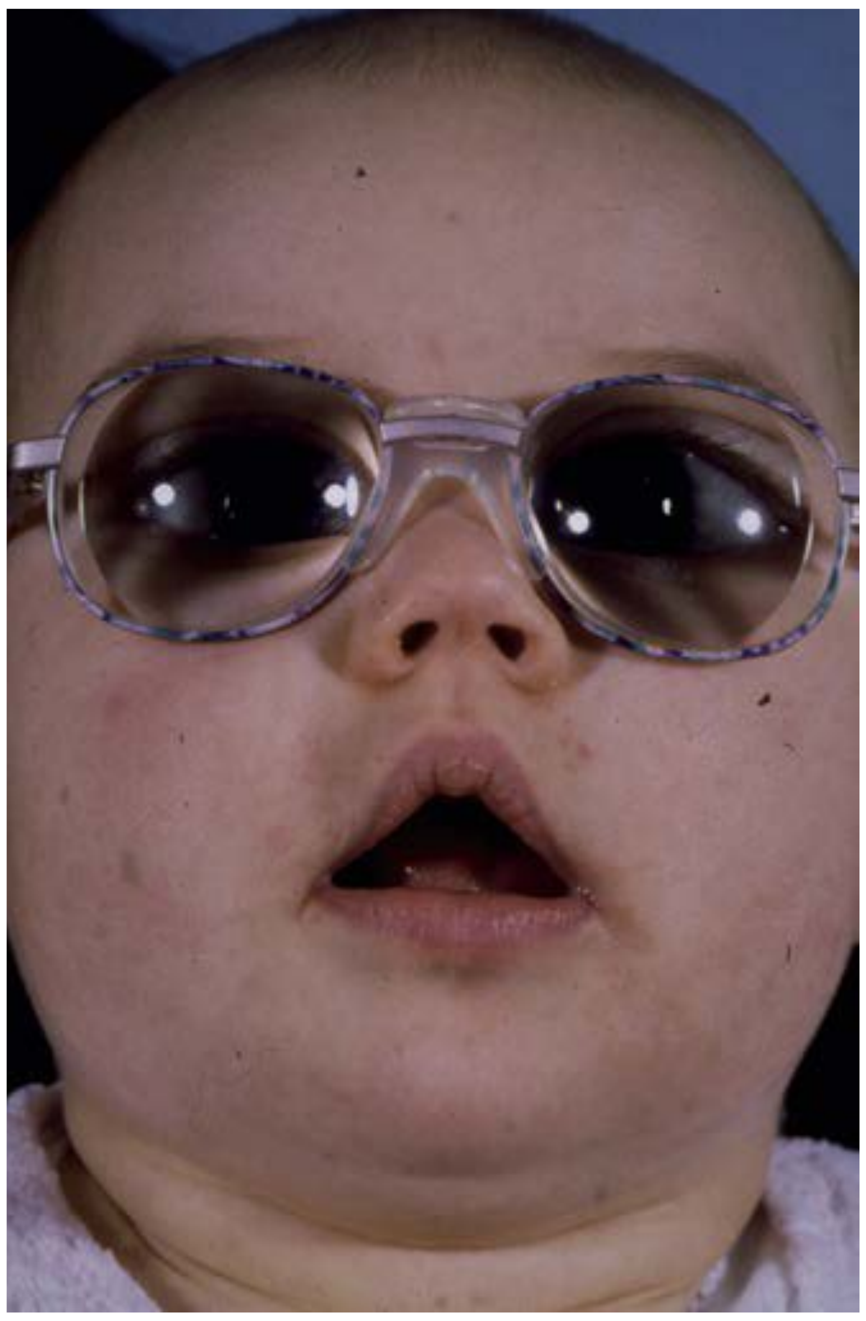

Fig. 28.2 An 8-month-old bilateral aphake wearing her spectacle correction.

As infants in the early stages of visual development require a focal length of around 30–50 cm in order to see a face, the power of the selected contact lens is usually 2–3 D greater than the ocular refraction. This overcorrection should be reduced at 18 months to 2 years when the toddler becomes more mobile and aware of distant objects. A reading correction or bifocals can be prescribed from around 3–4 years of age when the child starts preschool education.

PSEUDOPHAKIA

The use of intraocular lenses (IOLs) in the management of congenital cataract has now become more common as microsurgical techniques and IOL technology has improved. To obtain a satisfactory long-term refractive result, allowances must be made for growth of the eye, so pseudophakic eyes are deliberately left hypermetropic to allow for axial elongation with the corresponding myopic shift. The desired refractive result for infants undergoing surgery under the age of 10 weeks should be 8–9 dioptres (D) of hypermetropia, reducing to 4 D at 12 months of age and 2 D by 24 months. The final refractive status, following cessation of axial elongation, is aimed at emmetropia or low myopia (Lloyd et al., 2007). The recent Infant Aphakia Treatment Study (IATS) undercorrected the IOL power by 8 D for those infants operated between 4 and 6 weeks, and by 6 D for infants aged 7 or more weeks but less than 7 months (Lambert et al., 2010). The residual refractive error can then be corrected with a contact lens in the early months, with a 2 D overcorrection, gradually reducing lens power until the eye reaches an emmetropic state and contact lenses are no longer required or spectacles can be prescribed.

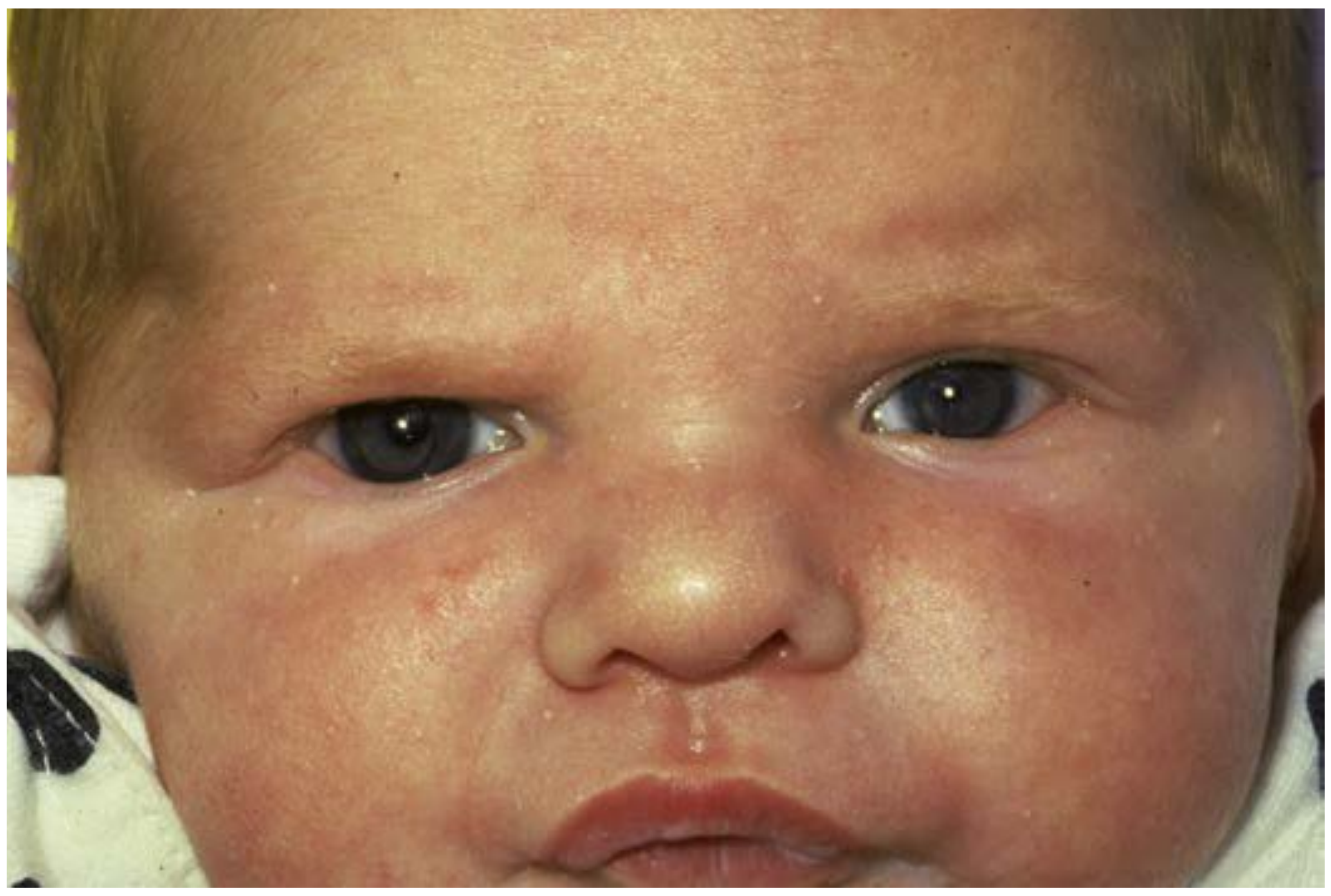

Fig. 28.3 A 3-week-old bilateral aphake wearing high-powered soft lenses of around +35.00 D.

HIGH MYOPIA

High myopia in infants and young children is not uncommon and correction with spectacles is the accepted practice. However, in high myopia, spectacles have the disadvantage of reducing the retinal image size, inducing peripheral distortion and reducing the effective visual field (especially with lenticulated lenses). Contact lens correction is warranted where spectacle correction is problematic or normal visual development is threatened. High myopia (>10 D) may be present from birth and is related to a number of ocular and systemic disorders (Jensen, 1997). High myopia is also associated with craniofacial anomalies, which can make the wearing of spectacles difficult (Fig. 28.4).

The myopic eye is larger than normal and tends to have a flatter than average corneal radius and larger corneal diameter. Adult-sized lenses can often be used in young infants and children. Myopia can also result from buphthalmos where the corneal diameter is much larger than normal (>12.5 mm) and so requires a flatter and larger lens.

Contact lenses in unilateral high myopia have been shown to be more satisfactory than spectacle lenses in the management of amblyopia in regard to cosmesis, comfort and treatment compliance (Mets and Price, 1981).

OCULAR MOTILITY DISORDERS

Contact lenses can be useful in the management of ocular motility disorders (Evans, 2006). Some uses include:

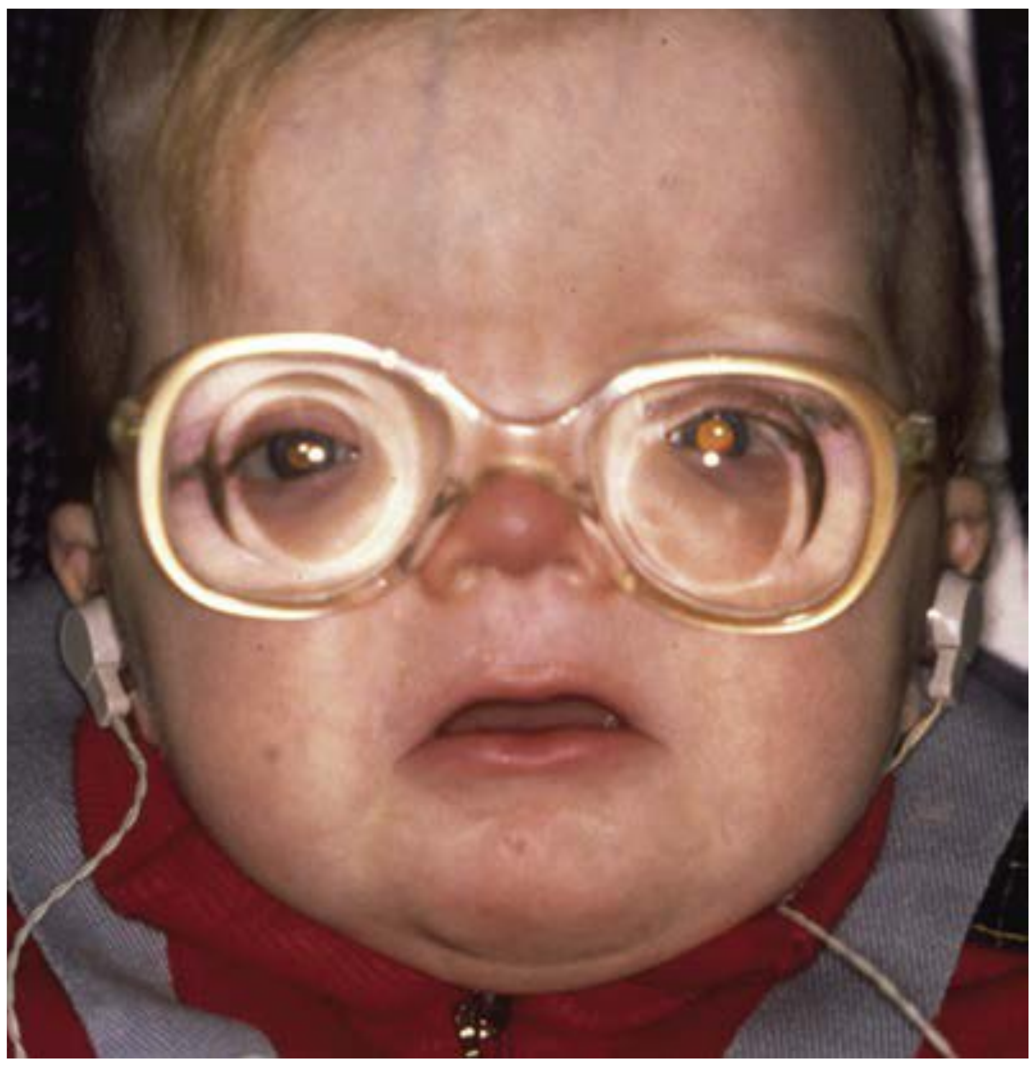

Fig. 28.4 An infant with a high myopia in association with a craniofacial anomaly.

TABLE 28.1 Estimated Hydrogel Lens Specifications Based on Age for an Aphakic Eye of Normal Size

Age (months)	BOZR (mm)	TD (mm)	Power (D)
1	7.00	12.00	+35.00
2	7.20	12.50	+32.00
3	7.50	13.00	+30.00
6	7.80	13.50	+25.00
12	8.10	13.50	+20.00

*These lenses would form the basis of a paediatric aphakic diagnostic fitting set.
BOZR = back zone optic radius; TD = total diameter.

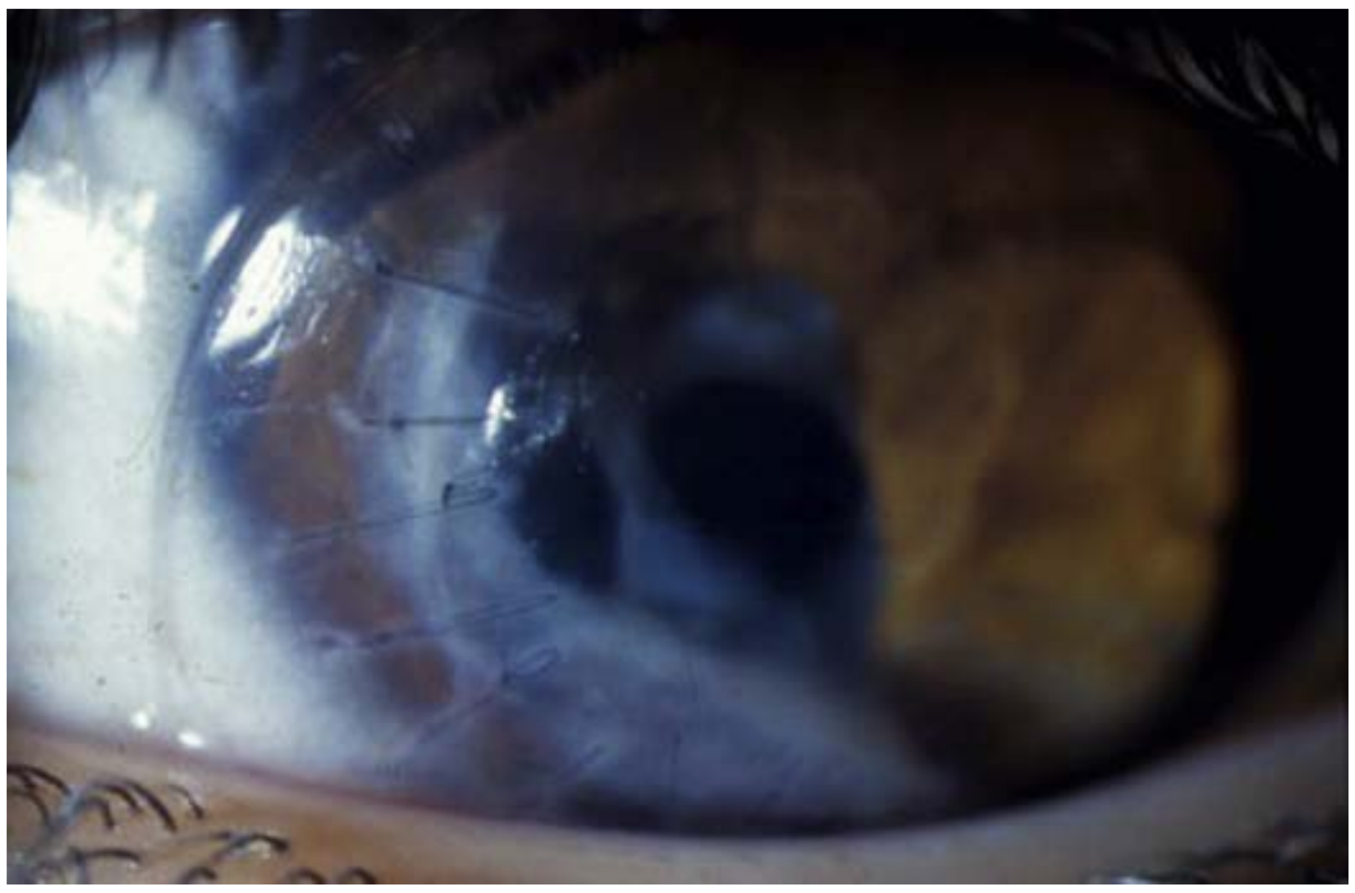

Fig. 28.5 An aphakic eye, following trauma and a full-thickness corneal laceration, fitted with a hydrogel toric contact lens.

- aniseikonia induced by anisometropia exceeding 6 D
- accommodative esotropia (older children)
- nystagmus
- occlusion.

IRREGULAR ASTIGMATISM

Irregular astigmatism derived from primary corneal ectasia is extremely rare in childhood. Most causes of corneal irregularity are secondary in nature – for example, following corneal infection or laceration (Fig. 28.5). Neutralization of irregular astigmatism is important during the visual development period so as to prevent deprivational amblyopia. The optimum form of contact lens correction in this situation is a rigid gas-permeable lens, although sometimes, if the irregularity is less severe, a toric soft lens may suffice. Rigid gas-permeable lenses have been shown to offer a useful refractive treatment alternative in children with traumatized eyes (Pradhan et al., 2014)

TINTED AND PROSTHETIC LENSES

The aim of this type of contact lens in paediatric use is to enhance visual performance by reducing the effect of photophobia or improving the cosmesis of the child by camouflaging an ocular defect. The most common reasons for fitting these lenses in childhood are:

- albinism
- aniridia
- achromatopsia
- iris defects, e.g. coloboma
- nanophthalmos or microphthalmos
- corneal anomalies, e.g. sclerocornea or Peter’s anomaly.

The fitting of these lenses is described in more detail in Chapter 22.

THERAPEUTIC LENSES

Silicone hydrogel lenses have been shown to be safe and efficacious for continuous-wear therapeutic use in children (Benoriene and Vogt, 2006). Therapeutic contact lens use in the paediatric population is similar to its use in adults – mainly for the relief of pain, promotion of corneal healing and protection of the cornea. An example of their use is reported by Maycock et al. (2008), where two cases of upper-eyelid entropion secondary to neonatal conjunctivitis resolved spontaneously following the insertion of bandage contact lenses. Previously early surgical intervention was advocated to correct the eyelid abnormality and prevent any permanent corneal scarring and visual loss. The fitting of therapeutic lenses is described in more detail in Chapter 29.

Elective Contact Lens Wear in Children

Contact lenses can be considered as an additional option to full-time spectacle wear or for use while participating in sporting activities for both myopic and hypermetropic children and teenagers. A study by Jones-Jordan et al. (2010) found that both rigid gas-permeable and soft contact lenses could be considered, although gas-permeable lenses took longer to adapt to and resulted in slightly less comfortable wearing times. Daily disposable contact lenses are particularly useful whilst participating in sporting activities, especially if wear is intermittent.

Efron et al. (2011) conducted an international survey to determine the types of contact lenses prescribed for infants (aged 0 to 5 years), children (6 to 12 years), and teenagers (13 to 17 years). Up to 1000 survey forms were sent to contact lens fitters in each of 38 countries between January and March every year for 5 consecutive years (2005–2009). Practitioners were asked to record data relating to the first 10 contact lens fits or refits performed after receiving the survey form.

Data were received relating to 105 734 fits (137 infants, 1672 children, 12 117 teenagers, and 91 808 adults [age ≥18 years]); the proportion of minors (<18 years old) fitted varied considerably between nations, ranging from 25% in Iceland to 1% in China (Fig. 28.6). Compared with other age groups, infants tend to be prescribed a higher proportion of rigid, soft toric, and extended-wear lenses, predominantly as refits for full-time wear, and fewer daily disposable lenses. Children are fitted with the highest proportion of daily disposable lenses and have the highest rate of fits for part-time wear. Teenagers have a similar lens-fitting profile to that for adults, the main distinguishing characteristic being a higher proportion of new fits. Orthokeratology fits represented 28% of all contact lenses prescribed to minors. Efron et al. (2011) concluded that patterns of contact lens prescribing to infants and children are distinctly different to those of teenagers and adults in a number of respects.

Contact lenses have also been proven to improve the quality of life of younger children (aged 8–12 years) and teenagers (aged 13–17 years). Studies (Walline et al., 2007a; Rah et al., 2010) have reported that contact lens wear significantly improved how both children and teenagers felt about their physical appearance and their ability to participate in activities. They concluded that children should be offered contact lenses as an option as often as teenagers are.

Ocular Response to Lens Wear

Walline et al. (2007b) assessed the ocular response to contact lens wear in 8–12-year-old children and 13–17-year-old teenagers. Subjects returned for biomicroscopy examination at 1 week, 1 month and 3 months after lens dispensing. The presence of conjunctival staining increased from 7% of the subjects at baseline to 20% of the subjects at 3 months, but the changes were similar between children and teens. No other biomicroscopy

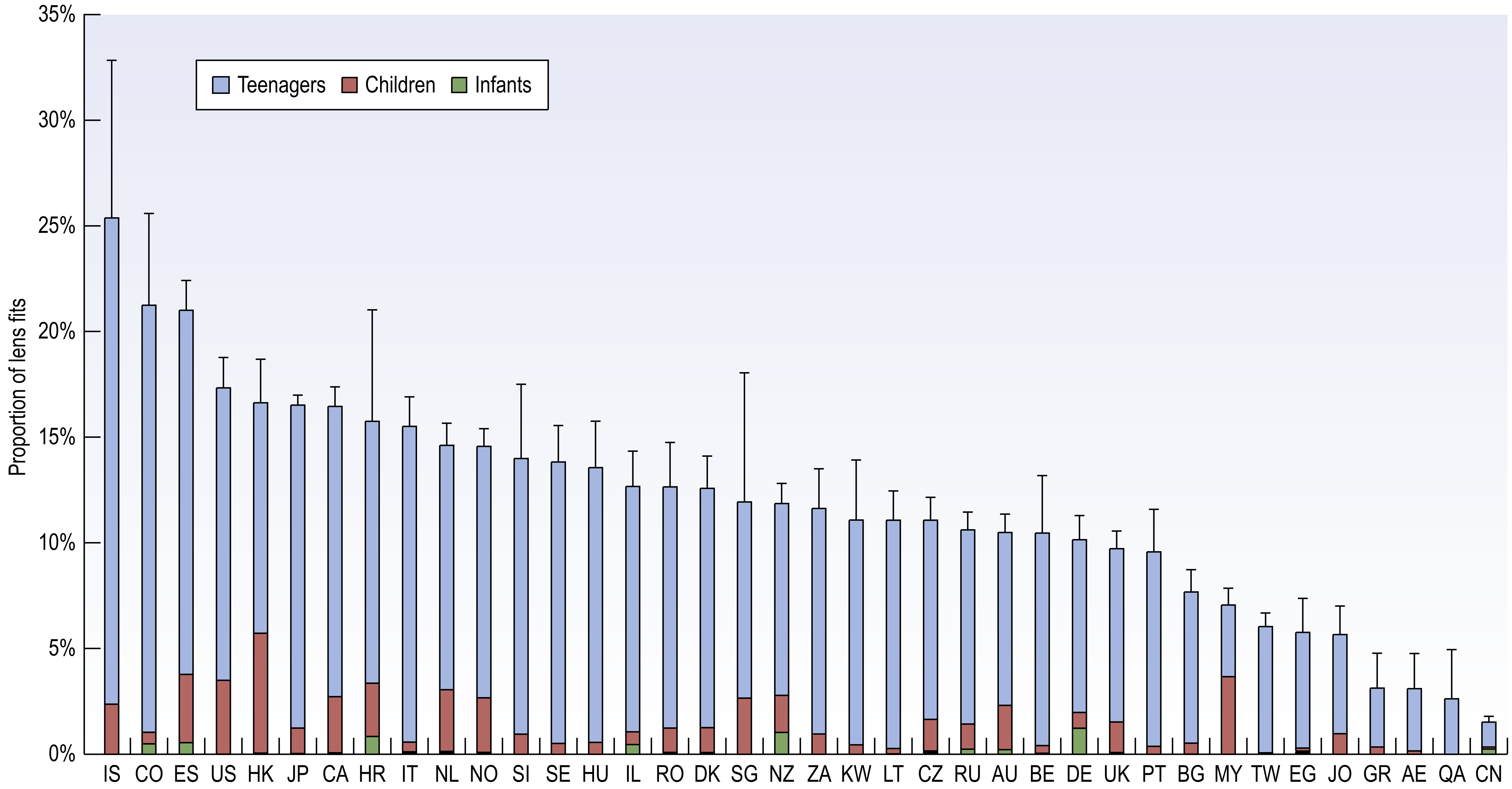

Fig. 28.6 Proportion all contact lenses fitted to infants, children, and teenagers in 38 countries between 2005 and 2009. Error bars represent ±95% confidence limits. AE = United Arab Emirates; AU = Australia; BE = Belgium; BG = Bulgaria; CA = Canada; CN = China; CO = Colombia; CZ = Czech Republic; DE = Germany; DK = Denmark; EG = Egypt; ES = Spain; GR = Greece; HK = Hong Kong; HR = Croatia; HU = Hungary; IL = Israel; IS = Iceland; IT = Italy; JO = Jordan; JP = Japan; KW = Kuwait; LT = Lithuania; MY = Malaysia; NL = Netherlands; NO = Norway; NZ = New Zealand; PT = Portugal; QA = Qatar; RO = Romania; RU = Russia; SE = Sweden; SG = Singapore; SI = Slovenia; TW = Taiwan; UK = United Kingdom; US = United States; ZA = South Africa.

signs increased significantly over the 3-month period. These findings suggest that contact lenses are a safe option for young children and can be routinely offered as a vision correction option, even for those as young as 8 years old.

Examination Techniques

ANTERIOR SEGMENT EXAMINATION

As with the adult patient, examination of the anterior segment is an important aspect of contact lens fitting and aftercare. A very simple method to determine the presence of corneal staining or ulceration is to use an ultraviolet lamp with fluorescein to determine the location and extent of the lesion. In babies, a major slit lamp can be used with the 'flying baby' technique (Fig. 28.7) and in infants and young children a hand-held slit lamp (Fig. 28.8) can be used to examine the anterior segment in more detail. Older children, from 3 or 4 years of age, can usually sit at a slit lamp, kneeling on a chair and grasping the headrest support bars.

KERATOMETRY

A hand-held automated keratometer can be used to determine the corneal radius of curvature in young infants and children too young to sit at a conventional keratometer (Fig. 28.9).

REFRACTION

Determination of the refractive error or a contact lens over-refraction is performed with retinoscopy using hand-held lenses or a paediatric trial frame in an older child. The use of a cycloplegic drug is recommended in those children with normal accommodative function. It is useful sometimes to dilate the pupil in aphakes or pseudophakes, where there is a small or displaced pupil, or where significant media opacity is apparent (e.g. posterior capsular thickening).

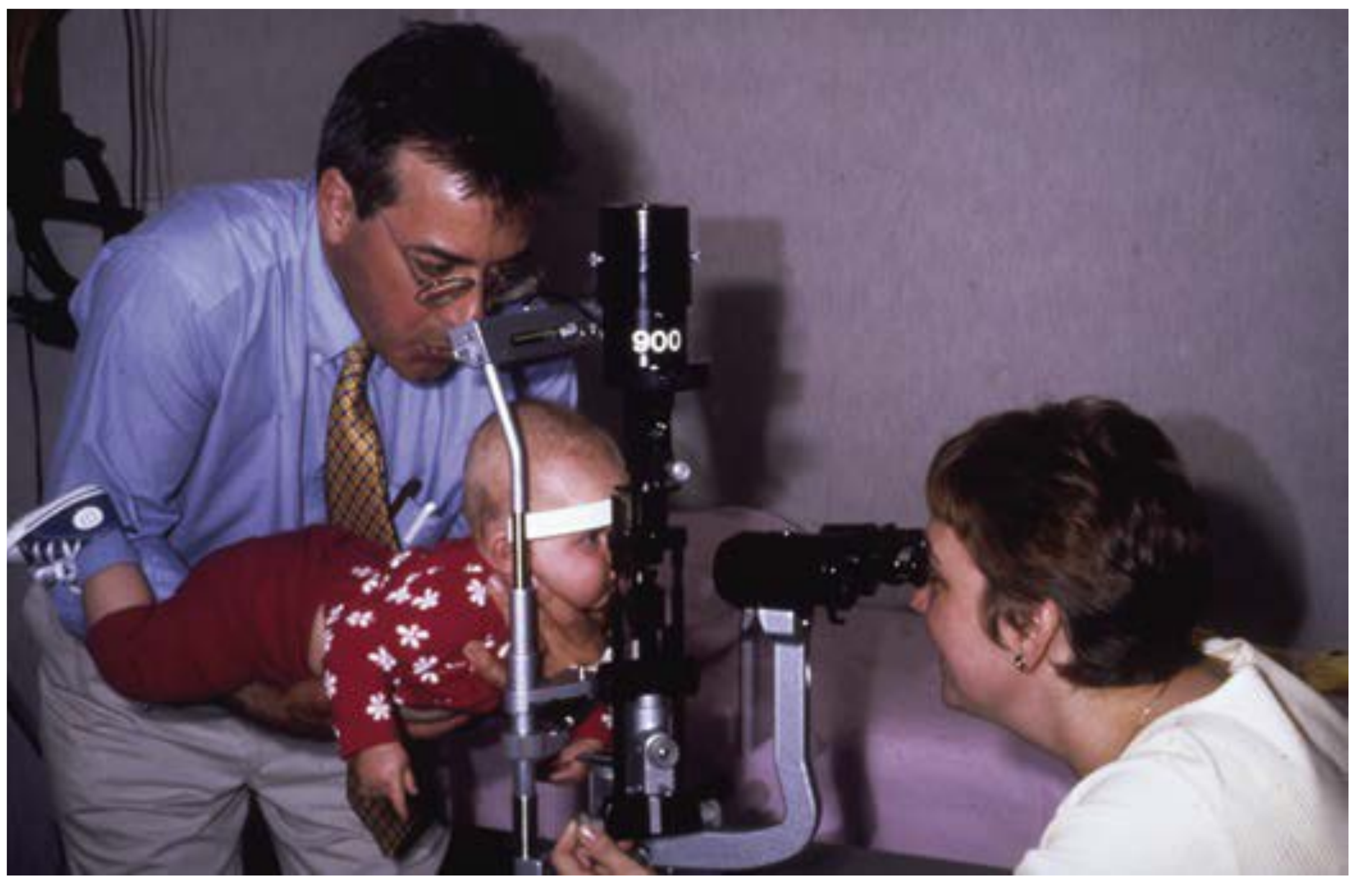

Fig. 28.7 The 'flying baby' technique of child support during ophthalmic examination.

BIOMETRY

Prior to cataract surgery, the axial length of the eye can be measured with ultrasound and the corneal radius of curvature by keratometry. These measurements can be used to determine

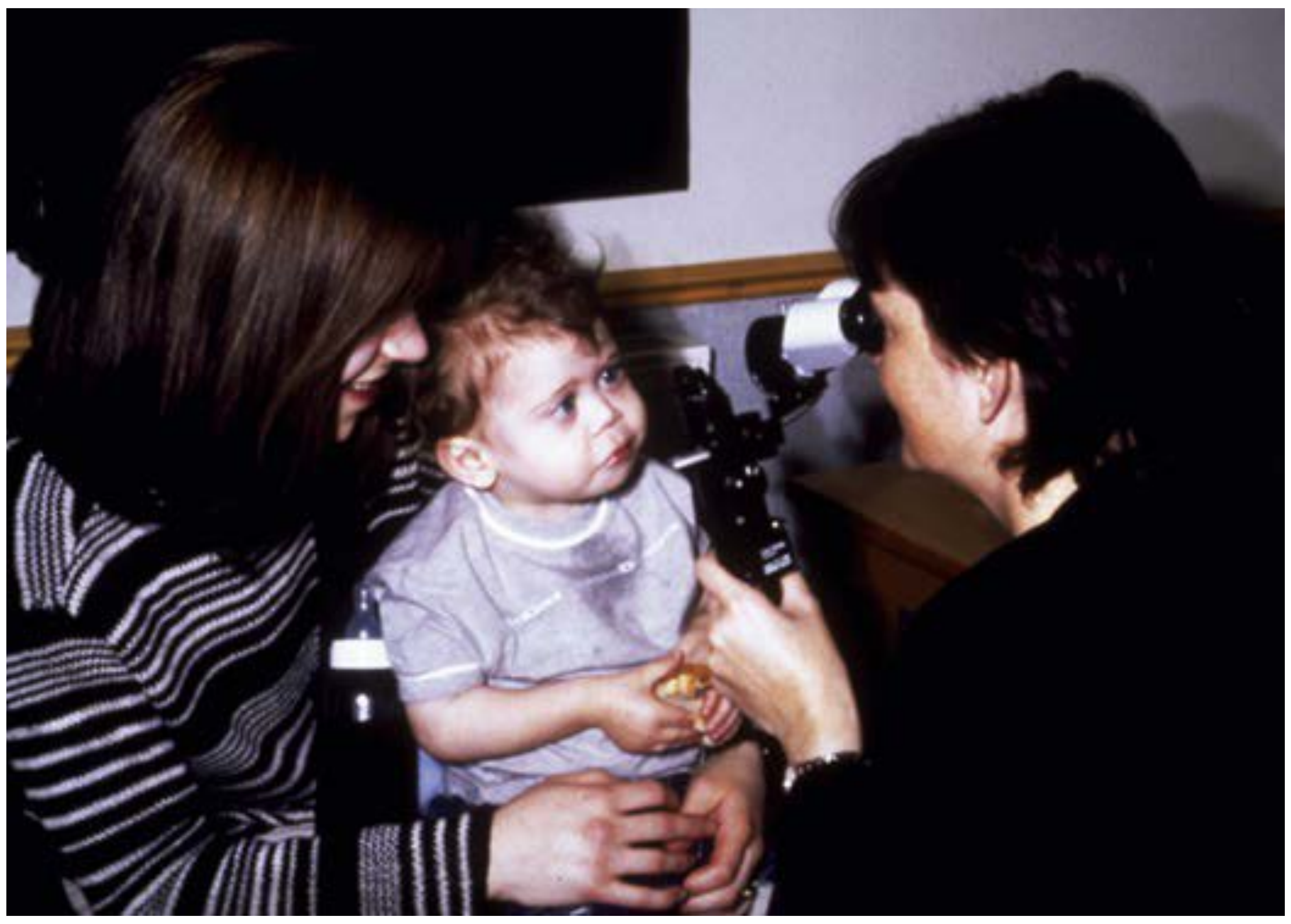

Fig. 28.8 Examination of the eye of a child, with a hand-held slit lamp.

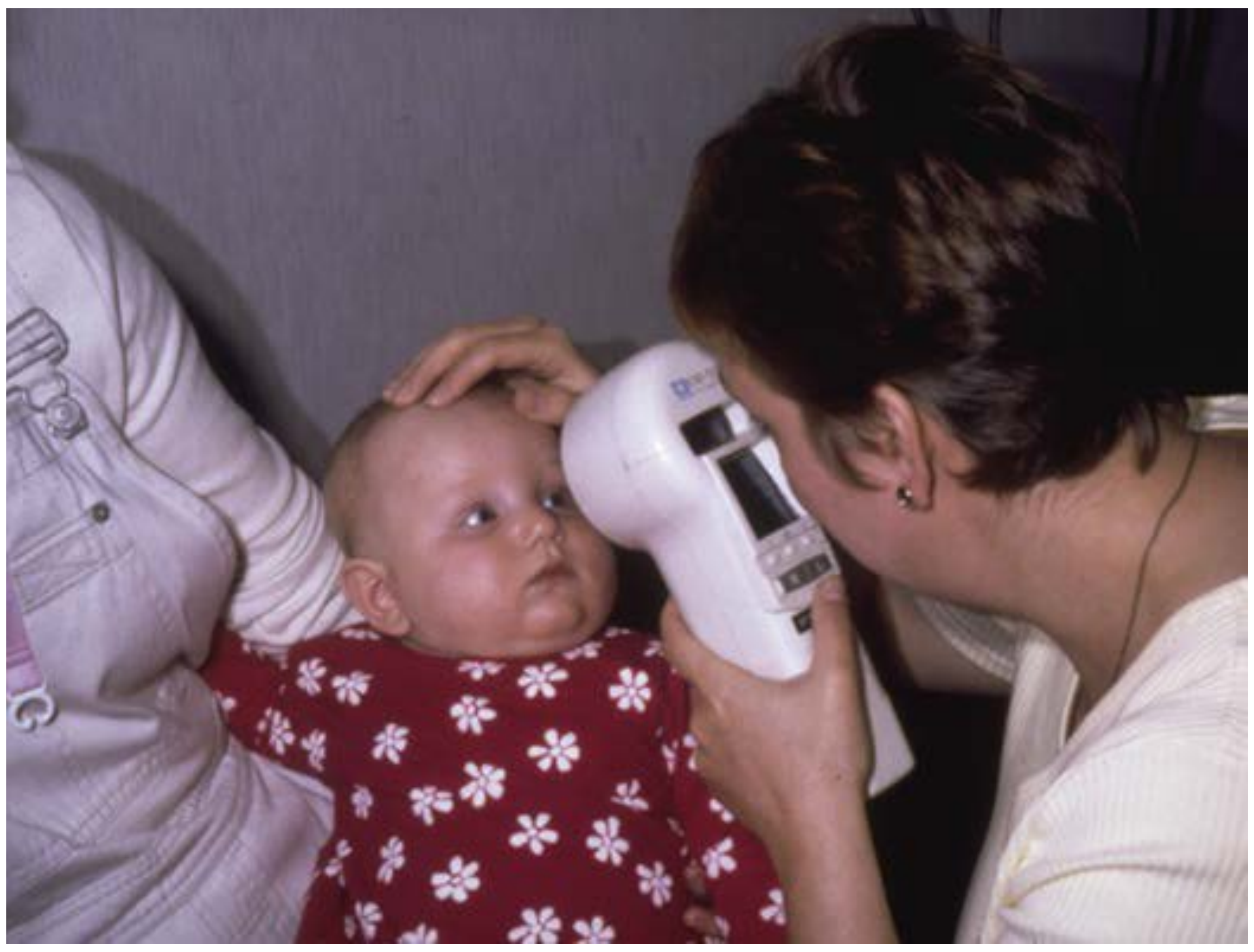

Fig. 28.9 Use of a hand-held autokeratometer on a baby.

the power of the contact lens required postoperatively by using an IOL calculation formula, such as Holladay, which can determine the ocular power at the corneal plane after surgery. This is particularly useful as it allows more or less correct specifications to be ordered, which alleviates the need for many lenses to be used at the initial fitting and allows for fewer lenses to be kept in stock.

Lens Selection

HYDROGEL LENSES

Hydrogel lenses are the most frequently used lens types in paediatric contact lens fitting. High-water-content lenses are usually selected as they can be worn for continuous or daily wear. Daily wear should be considered where possible so as to reduce the risk of infection, as oxygen transmission can be reduced through high-powered lenses such as those used to correct aphakia (Amaya et al., 1990). However, as babies and young children sleep during the daytime, the lenses can remain in the eye during these periods.

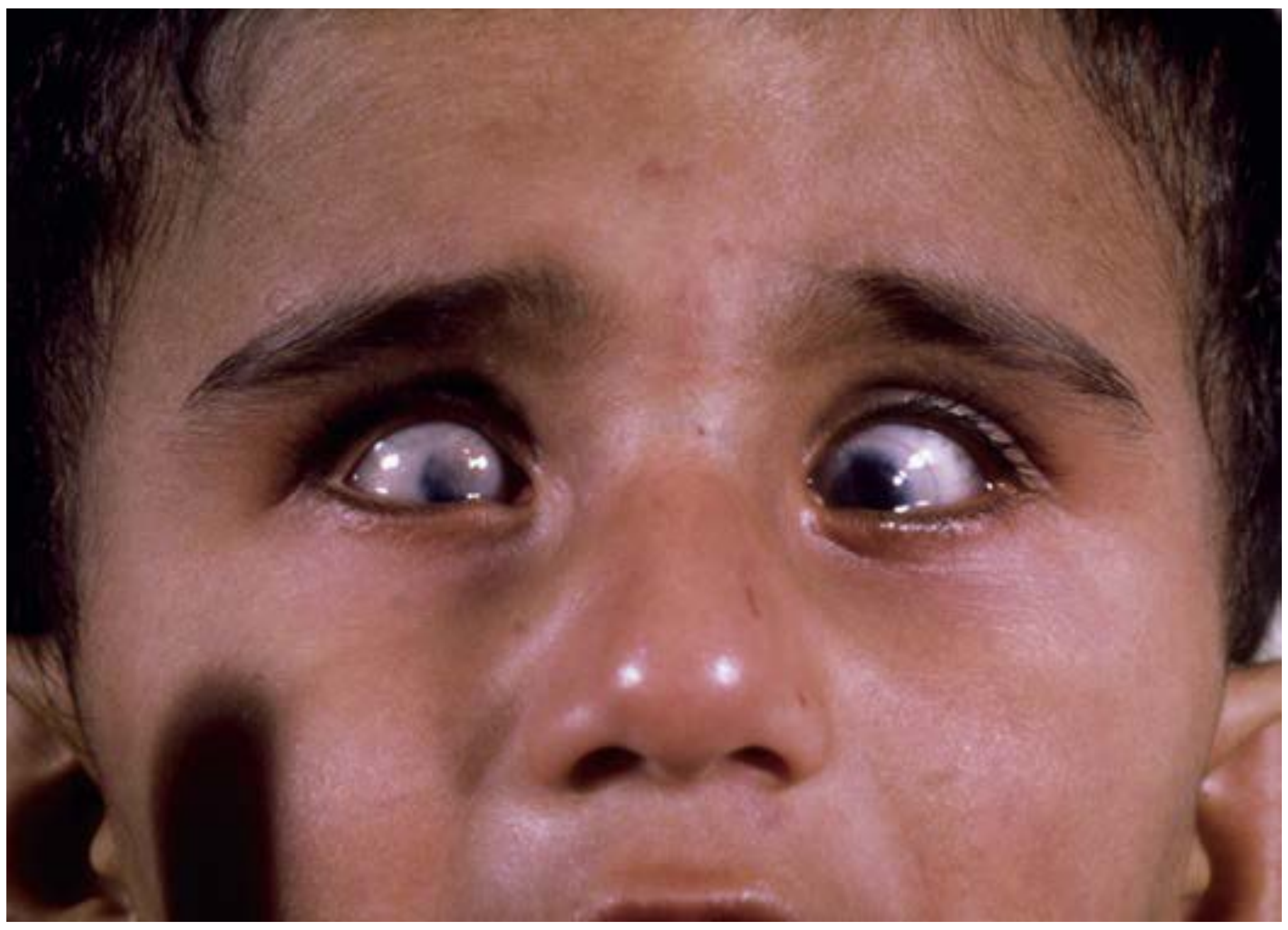

Fig. 28.10 A silicone rubber lens fitted to the left aphakic eye of an infant with microcornea; a soft lens had failed owing to lens dehydration.

Lenses are usually fitted according to age or based on keratometry readings and corneal diameter.

The advantages of soft lenses are as follows:

- They are custom made in a range of radii, overall size, power and water content
- They are initially comfortable for the child
- Parents tend to be less apprehensive about inserting a hydrogel lens into the eye of a baby or young child.

The disadvantages of soft lenses are as follows:

- They do not correct significant corneal astigmatism
- Insertion can be difficult, especially for minus lenses, where there is considerable lid squeezing or a very small palpebral aperture
- Hydrogel lenses are prone to dehydration – babies have relatively dry eyes owing to their low blink rate
- There may be frequent lens loss as a result of eye rubbing and dehydration.

SILICONE RUBBER LENSES

Silicone rubber lenses are often used in the correction of refractive errors in babies and young children, and are particularly useful where there is frequent lens loss or a dry ocular surface (Fig. 28.10). The lens fit can be checked using fluorescein and ultraviolet light. A period of settling, for example 30 minutes, is required (Visser, 1997).

Silicone rubber lenses have the following advantages:

- Very high oxygen permeability
- Not susceptible to dehydration on the eye
- Less susceptible to damage
- Not easily rubbed out
- Easier to insert than hydrogel lens owing to increased rigidity.

Silicone rubber lenses have the following disadvantages:

- Range of parameters and availability are limited
- Need to be fitted precisely and require more chair time owing to longer settling periods
- Negative pressure effects can cause adhesion to the cornea if the lens is too tight
- Surface coating degenerates, so lenses have a relatively short life span
- More expensive than hydrogel and rigid lenses.

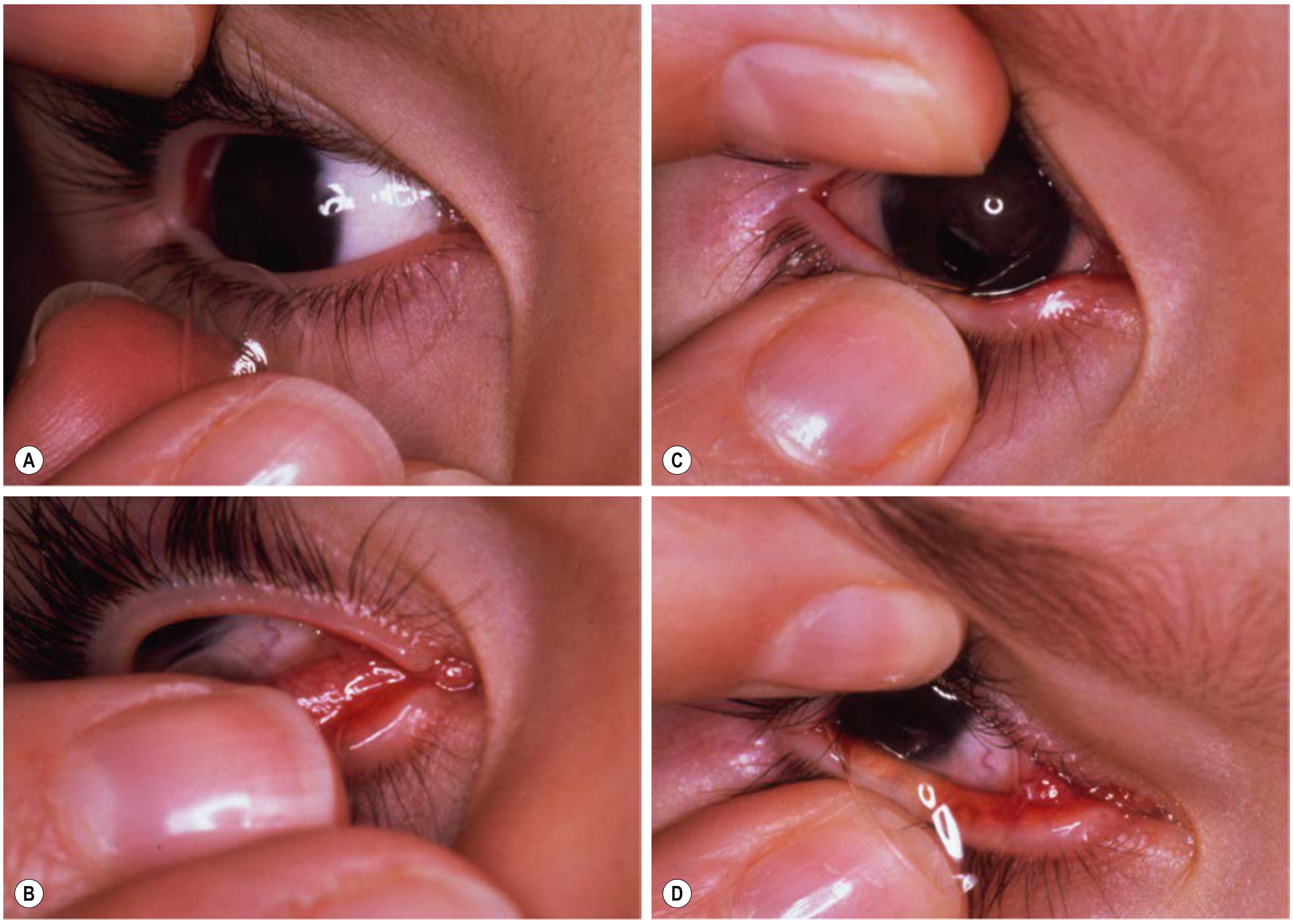

Fig. 28.11 Paediatric contact lens insertion technique. (A) Hold the lens and upper lid prior to lens insertion. (B) The lens is inserted into the eye with the forefinger. (C) Positioning of fingers on the upper and lower lids prior to removal. (D) The lens is removed by applying gentle pressure and squeezing the lids together.

However, these lenses are becoming increasing difficult to obtain as silicone hydrogel materials have developed.

SILICONE HYDROGEL LENSES

Silicone hydrogel lenses are now readily available in the range of base curves, diameters and powers that are required for fitting complex refractive error in young eyes; they are now often the lens of first choice and are particularly useful as they have similar properties to silicone rubber lenses. The use of custom-made silicone hydrogel lenses is discussed further in Chapter 27.

RIGID LENSES

The development of automated hand-held keratometry and rigid lens design has led to the increased use of rigid lenses for paediatric use. They have been successfully used for the management of aphakia in infants and can be fitted without the need for general anaesthesia (Amos et al., 1992) and for correcting high myopia and irregular astigmatism following corneal scarring and trauma (Shaughnessy et al., 2001).

Rigid lenses have the following advantages:

- They are available in a large range of materials and parameters.
- They correct corneal astigmatism.
- They are durable.
- Rigidity can help ease insertion and removal.

They have the following disadvantages:

- They are not usually suitable for continuous wear.
- Parents/carers can be more apprehensive about inserting rigid lenses.
- There is a risk of abrasion if insertion is difficult.
- Initial discomfort may be a problem in older children.

Rigid lenses are now available in hyperoxygen-permeable materials, designs and powers suitable for the treatment of paediatric aphakia and seem to provide adequate corneal oxygenation so that they can be used on a 1-week extended-wear basis (Saltarelli, 2008).

Handling of Lenses

A modified technique for insertion and removal is required in the young eye and this technique is shown in Fig. 28.11.

Some general points to consider when handling contact lenses in babies and young children are as follows:

- Lenses are easier to insert and remove with the child lying down on a firm, flat surface, e.g. an examination couch.

- Babies can be swaddled in a blanket to make handling easier.
- It is far easier to learn how to handle lenses on a young infant than on a more active baby or toddler. It is therefore important to encourage parents and carers to undertake lens handling from the outset of lens fitting.
- Parents/carers should be advised to keep to regular times for handling, so that it becomes accepted as part of daily routine.
- If handling is difficult in young infants, lenses can always be inserted or removed during sleep.
- Handling often becomes more difficult from 18 months onward. Bilateral aphakes can start to use spectacles at this point and anisometropes can use a spectacle correction when occluded.
- Cooperation may be extremely limited in children aged between 2 and 5 years when fitting lenses for the first time. Spectacles may have to suffice in this age if the benefits of contact lenses are outweighed by the distress caused to the child by handling.

Common Aftercare Problems

In addition to lens fitting and handling problems, some other common problems include:

- Red or sticky eye – this can be due to numerous causes, including tight-fitting lens, infection, inflammation or allergic reaction. Parents/carers should be instructed to remove the lens immediately and to seek urgent advice from a contact lens practitioner or ophthalmologist.
- Neovascularization – especially where thick hydrogel lenses have been used for continuous wear. Consider refitting with rigid or silicone hydrogel lenses.
- Papillary conjunctivitis – eye rubbing is often a sign of ocular irritation due to an allergy to care solutions or protein deposition on lenses. Management is similar to that in adult patients (see Chapter 40).
- Glaucoma – long-term monitoring of eyes after congenital cataract surgery is essential as up to two-thirds will develop glaucoma or become glaucoma suspects by 10 years after surgery (Lambert et al., 2013). Intraocular pressure can be measured on babies and young children with a hand-held non-contact tonometer (e.g. Pulsair) or rebound technology tonometer (e.g. iCare) and this is advised at each visit.
- Other coexisting ophthalmic disease – regular fundoscopy should be performed to exclude the presence of, for example, retinal detachment, which is associated with high myopia and Marfan's syndrome.

ACKNOWLEDGEMENT

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Access the complete references list online at http://www.expertconsult.com.

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29

Therapeutic Applications

NATHAN EFRON | SUZANNE E EFRON

Introduction

The concept of a protective eye bandage originated in the first century ad, when Celsus reportedly applied a honey-soaked linen to the site of a pterygium removal to prevent symblepharon development (Weiner, 1994). The therapeutic use of contact lenses goes back to the 1880s when Eugene Kalt (1861–1941) fitted a case of keratoconus. Since then, all types of contact lenses have been used as therapeutic aids. The term 'therapeutic contact lens' has become synonymous, for many, with a soft plano 'bandage' lens, however, the therapeutic use of contact lenses is much wider than that.

Indications

A contact lens may be fitted therapeutically for the relief of pain or discomfort, to assist the healing of injured or diseased ocular tissue or to improve vision in the case of unusual or distorted corneal shapes. Sometimes a therapeutic lens simultaneously addresses more than one clinical problem; it may in addition be used to correct a refractive error and has the potential to deliver ophthalmic drugs to the ocular surface.

UNUSUAL OR DISTORTED CORNEAL SHAPE

Congenital or developmental abnormalities of corneal topography, such as primary corneal ectasia (e.g. keratoconus and keratoglobus) and cornea plana (Fig. 29.1), typically result in visual loss that is usually corrected with rigid forms of contact lenses – either corneal or scleral. Some success in correcting cases of corneal ectasia has been reported with custom-designed soft lenses, such as the KeraSoft IC lens (Lagina, 2015).

These conditions are rare but the patient is usually highly motivated to wear such lenses. Surgical treatment of severe keratoconus and keratoglobus may be technically difficult and, in the case of corneal transplantation, despite procedural advances such as deep anterior lamellar keratoplasty (DALK), there is still a risk of allograft rejection, which can compromise the final outcome of the operation. Other newer procedures, such as the implantation of intrastromal corneal rings, have been given FDA approval. However, contact lens management, if successful, is nearly always to be preferred. Optimal visual correction can generally be provided and the lenses can be changed in design and power as the underlying condition and other ocular factors evolve.

RELIEF OF PAIN

Corneal epithelial pain can be severe and disabling. A simple corneal abrasion usually heals quickly and needs no help from the clinician, but a persistent or recurrent epithelial failure may benefit from the fitting of a soft bandage lens of either hydrogel or silicone hydrogel material, which acts as a mechanical barrier between the injured corneal surface and the lid. Bandage lenses are routinely used for pain relief following refractive surgery procedures where the epithelium is removed (see Chapter 30).

RECURRENT EROSION SYNDROME

Minor trauma to the cornea may predispose to this condition. Very often, corneal epithelial basement membrane dystrophy (such as Cogan's microcystic dystrophy or map-dot-fingerprint dystrophy) is found to be present; this is a bilateral condition, so both eyes should always be carefully examined. The eye with the erosion often becomes acutely painful when the eyes are opened during the night or when waking, for at that time tear production is minimal and friction maximal,

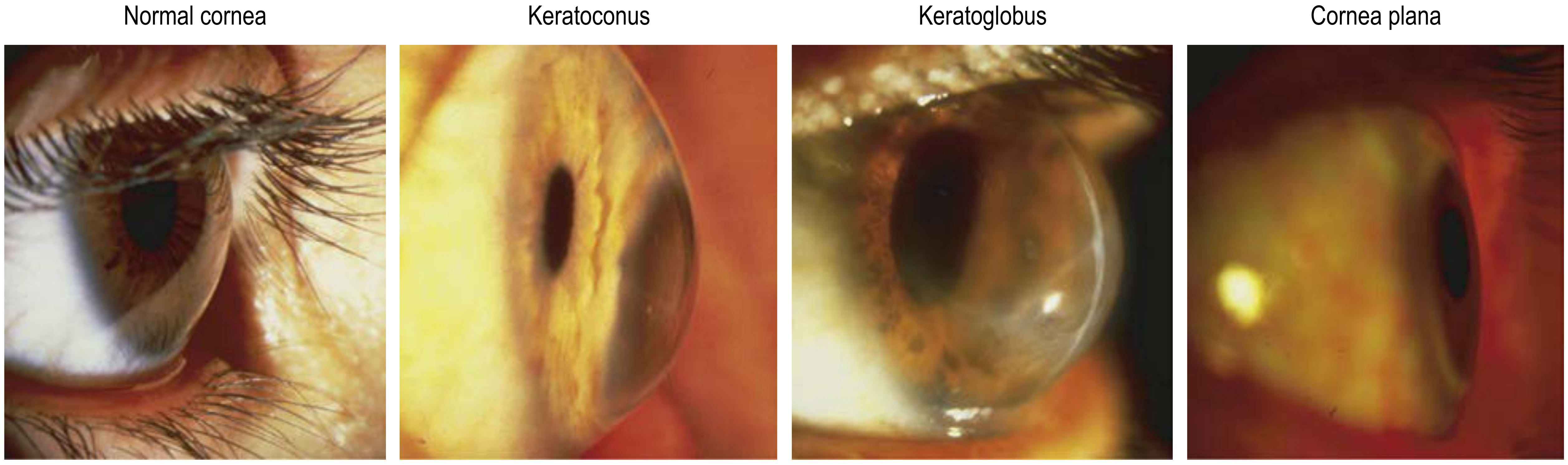
Normal cornea
Keratoconus
Keratoglobus
Cornea plana

Fig. 29.1 Unusual corneal shapes. (Images from left to right courtesy of Hilmar Bussaker, J. Miller, Ignacio Burgos and W. Vreugdenhil, respectively; all Bausch & Lomb Slide Library.)

so that the lid margin pulls on the unstable patch of epithelium, sometimes causing epithelial disruption. A contact lens interposed between cornea and lid can reduce the friction (Williams and Buckley, 1985; Liu and Buckley, 1996). Three months of extended-wear bandage lens use may be sufficient to avoid the recurrence of corneal erosions in the majority of cases (Fraunfelder and Cabezas, 2011). Anterior stromal puncture is a low-cost alternative; however, it carries the risk of corneal perforation.

CORNEAL DYSTROPHIES INVOLVING THE EPITHELIUM

Epithelial basement membrane dystrophy is by far the most common epithelial dystrophy, but other dystrophies that can involve the corneal epithelium also cause pain or discomfort that can be relieved with soft lenses. They include Reis–Bücklers' dystrophy, Meesman's dystrophy, lattice dystrophy and Fuchs' dystrophy; in the last of these the failing corneal endothelium cannot prevent stromal oedema and bullous change in the epithelium (Andrew and Woodward, 1989). Thygeson's superficial punctate keratopathy is not recognized as a dystrophy but is appropriately considered here; this condition can sometimes be managed successfully with hydrogel lenses (Forstot and Binder, 1979), although weak topical steroid is a more usual form of management.

FILAMENTARY KERATITIS

A 'wet' form of filamentary keratitis sometimes occurs without tear volume deficiency in herpes simplex keratitis, recurrent erosion, dystonia and Theodore's superior limbic keratoconjunctivitis. This condition often responds well to the use of hydrogel lenses (Bloomfield et al., 1973). The more usual 'dry' form of filamentary keratopathy occurs in tear deficiency, although contact lenses have little part to play in the management of this form of the disease. Scleral lenses have, however, been used successfully in 'dry' filamentary keratitis.

CORNEAL DEGENERATIONS INVOLVING THE EPITHELIUM

Conditions such as Salzmann's nodular degeneration, rosacea keratopathy and atopic keratoconjunctivitis – with or without ectasia – can sometimes be so uncomfortable that a therapeutic contact lens is indicated. In such cases, a lens will probably also improve visual potential. Concurrent conjunctival disease and tear abnormality may well benefit from the use of a scleral lens.

CORNEAL DEGENERATIONS INVOLVING THE ENDOTHELIUM

Corneal trauma or surgery that has depleted endothelial functional reserves can lead to epithelial bullous keratopathy, the discomfort of which is often amenable to management with hydrogel or silicone hydrogel lenses. In some cases, a corneal transplant will subsequently provide a cure. Formerly this meant a full-thickness procedure but recently a method of replacing the endothelium, Descemet's stripping endothelial keratoplasty (DSEK) has been described and is gaining acceptance. A combination of phototherapeutic keratectomy and therapeutic contact lens wear for a limited period has been proposed in cases of bullous keratopathy not suitable for corneal transplantation (Lin et al., 2001).

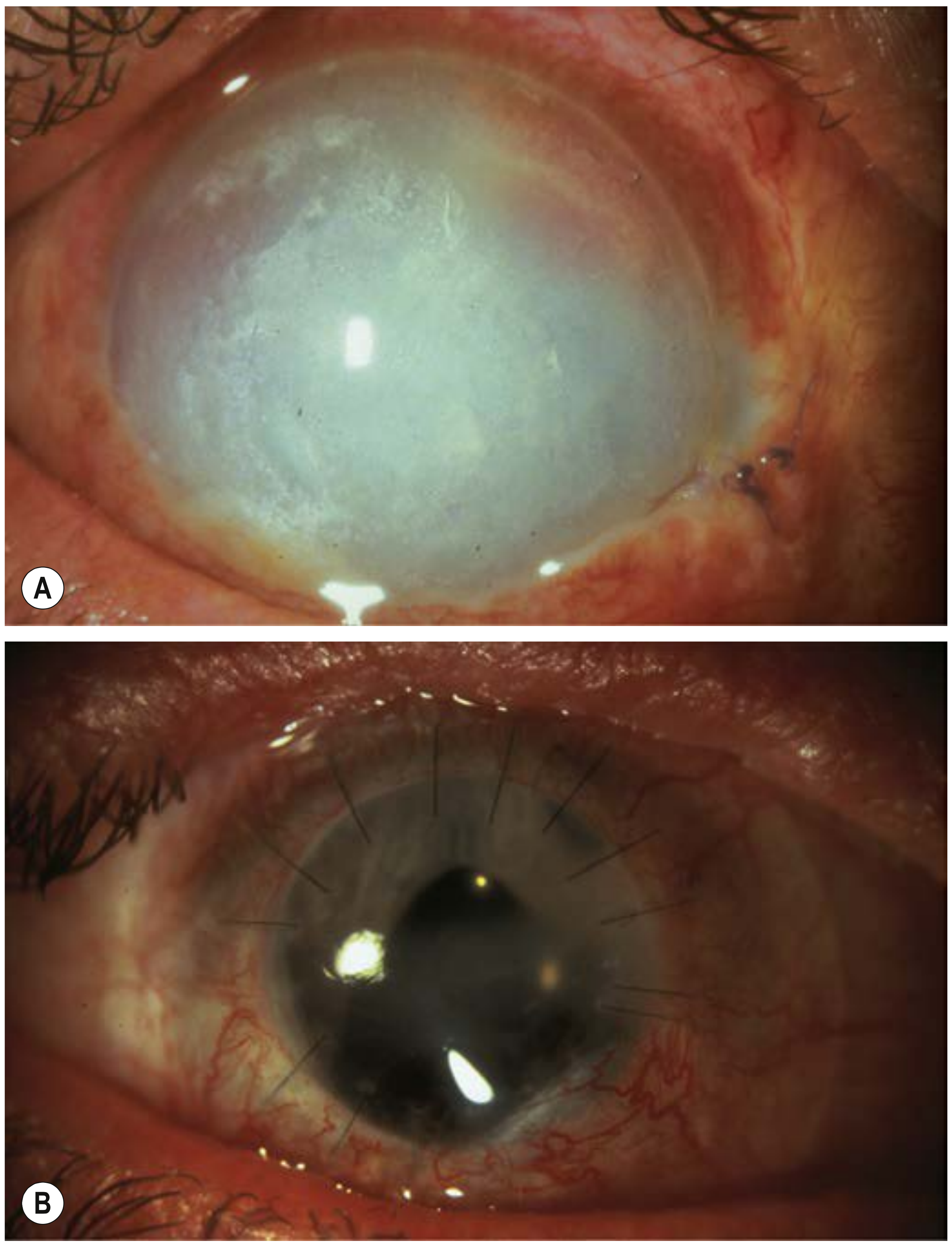

Fig. 29.2 A 21-year-old woman suffered a sodium hydroxide chemical burn to the right eye. (A) After surgery (tenonplasty) a 12 mm diameter polymethyl methacrylate (PMMA) lens was glued to the cornea for 1 year (pictured here), after which a perforating keratoplasty was performed. (B) A high-water-content soft bandage lens was worn for 6 months to cover a persistent epithelial defect. The cornea remained clear and re-epithelialized. (Courtesy of W. Vreugdenhil, Bausch & Lomb Image Library.)

CHEMICAL INJURIES

Much has been written about the use of contact lenses in the management of chemical injuries, especially alkali burns (Fig. 29.2).

However, research into the role of the limbal stem cell origin of the corneal epithelium has shown that contact lens coverage of the chronic epithelial defect cannot prevent the colonization of the cornea by conjunctivally derived epithelial cells. There are, however, some situations in which a contact lens can assist healing, supported by topical medications, although very close supervision is required.

CICATRICIAL CONJUNCTIVITIS

It is clear that no type of contact lens can prevent conjunctival shrinkage. However, a scleral lens or ring can be used to support the fornices during the healing process following mucous membrane transplantation. More usually, contact lenses are fitted to protect the cornea from the hostile environment created by the disease (see below).

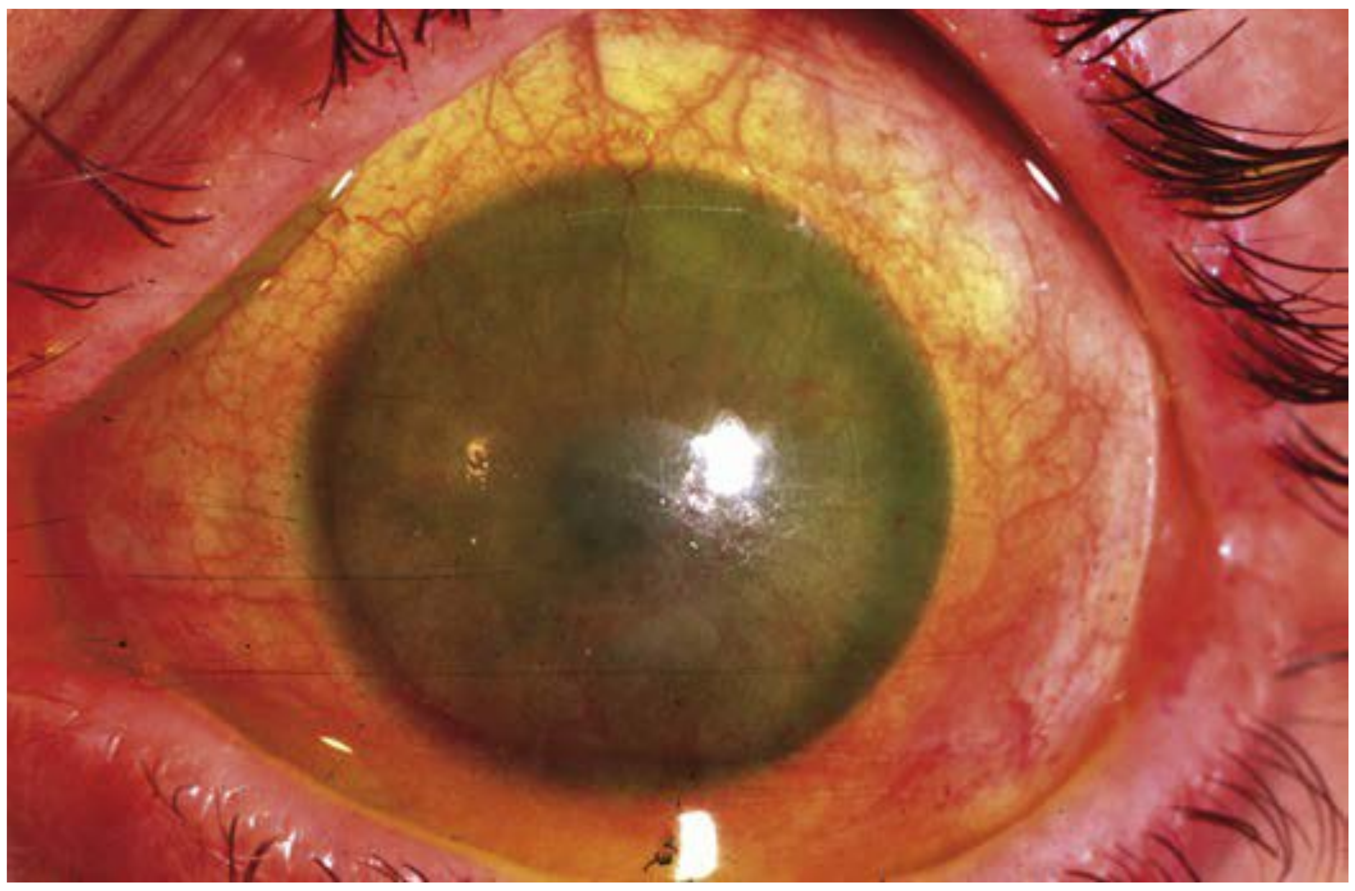

Fig. 29.3 Severe Stevens–Johnson disease. The eye is fitted with a sealed gas-permeable scleral lens giving full corneal fluid coverage to maintain long-term hydration. There is extensive corneal neovascularization, which is not contact lens-induced but rather part of the disease process that was present before embarking on scleral lens fitting. (Courtesy of Ken Pullum.)

TEAR DEFICIENCY

Tear deficiency is usually managed with the use of tear supplement drops and lubricating ointments, and sometimes the lacrimal puncta or canaliculi are deliberately blocked. Contact lenses are less often used. At one time it was thought that a high-water-content hydrogel lens could help to rehydrate a dry eye, but this is not possible as the lack of tears causes such a lens to dry and fall out of the eye. Silicone hydrogel (low-water-content) lenses are generally more successful in an abnormally dry ocular environment. The lens of choice is often a scleral lens, which covers the entire exposed surface of the eye, maintains a precorneal fluid reservoir and limits the evaporation of tears from the ocular surface.

PROTECTION FROM LIDS AND ENVIRONMENT

If the lids are deficient (e.g. congenitally or following trauma or surgery) or immobile (e.g. following seventh-nerve palsy), the eye is exposed and dry. The corneal epithelium becomes eroded and undergoes dysplasia, and blood vessels will invade the previously clear stroma, unless protection can be given. Possibilities include a temporary or permanent tarsorrhaphy, temporary paralysis of the levator palpebrae superioris muscle using botulinum toxin and the use of therapeutic contact lenses.

The lids themselves may constitute the challenge. They may be inturned (entropic), so that the lashes touch the globe (trichiasis), or the tarsal conjunctiva – especially the area adjacent to the lid margin – may be keratinized. Both situations are found in chronic cicatrizing disease, such as Stevens–Johnson disease (Fig. 29.3) and cicatricial pemphigoid, and following chemical injury.

Keratinization without entropion is a feature of atopic keratoconjunctivitis. Most soft lenses will not survive in this type of environment, rapidly becoming decentred and often falling out of the eye. There is a case for rigid lenses, especially lenses of large (limbal) diameter, but the first choice will often be a scleral lens.

When the cornea is insensitive, as occurs in trigeminal anaesthesia – such as following surgery for acoustic neuroma (Fig. 29.4) and in herpes zoster involving the ophthalmic division – the condition of neurotrophic keratitis is commonly seen and great care must be taken when fitting contact lenses. Congenital corneal anaesthesia and neurotrophic keratitis are extremely rare but very problematic conditions, which may be managed by frequent topical lubrication and bandage or scleral contact lenses (Mantelli et al., 2015) The danger in all cases of anaesthesia is that the reduced sensation will fail to alert the patient to complications such as retained foreign body, epithelial erosion and infection.

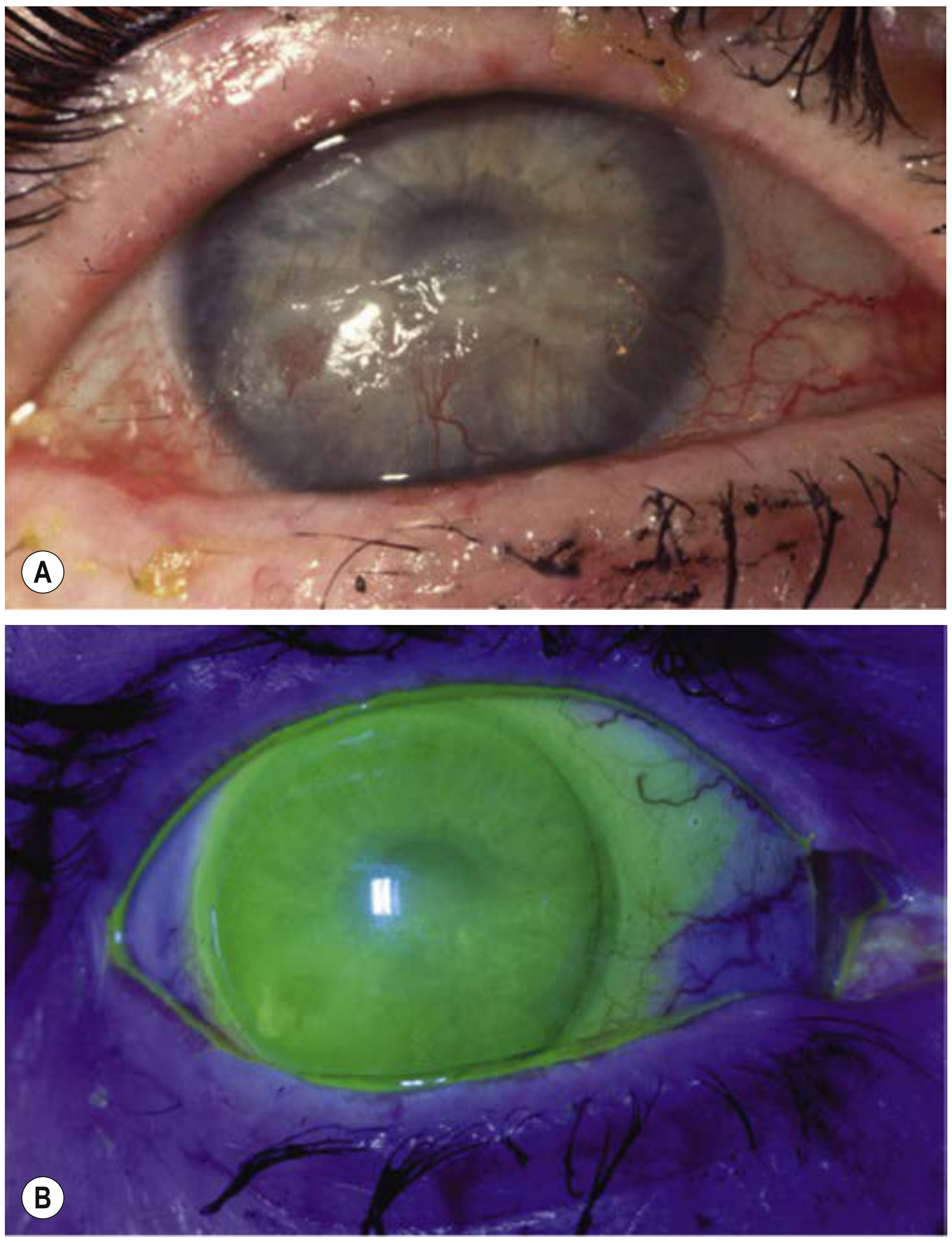

Fig. 29.4 Severe exposure keratitis consequent to loss of lid closure function following an acoustic neuroma. (A) Viewed in white light without the lens, a severe exposure keratitis and neovascularization are evident. (B) A sealed gas-permeable scleral lens was prescribed for overnight wear. The precorneal fluid reservoir extends just beyond the limbus on the temporal side, and slightly further on the nasal side, providing an environment to enhance healing and maintain corneal hydration. The cosmetic appearance is improved by replacement of the highly irregular cornea with a smooth lens front surface and regular light reflex. The lens itself is barely visible: the edge can just be seen at the inner canthus. (Courtesy of Ken Pullum.)

Patients with neuroparalytic keratopathy – that is, corneal disease secondary to exposure (e.g. in severe proptosis or ectropion, or resulting from facial nerve palsy) – are initially best managed with lid taping, tarsorrhaphy or botulinum toxin-induced ptosis. There is sometimes a role for therapeutic contact lenses.

MAINTENANCE OF A PRECORNEAL TEAR RESERVOIR

Where the eye cannot support a coherent tear film – for example, when a mucus abnormality or epithelial dysplasia

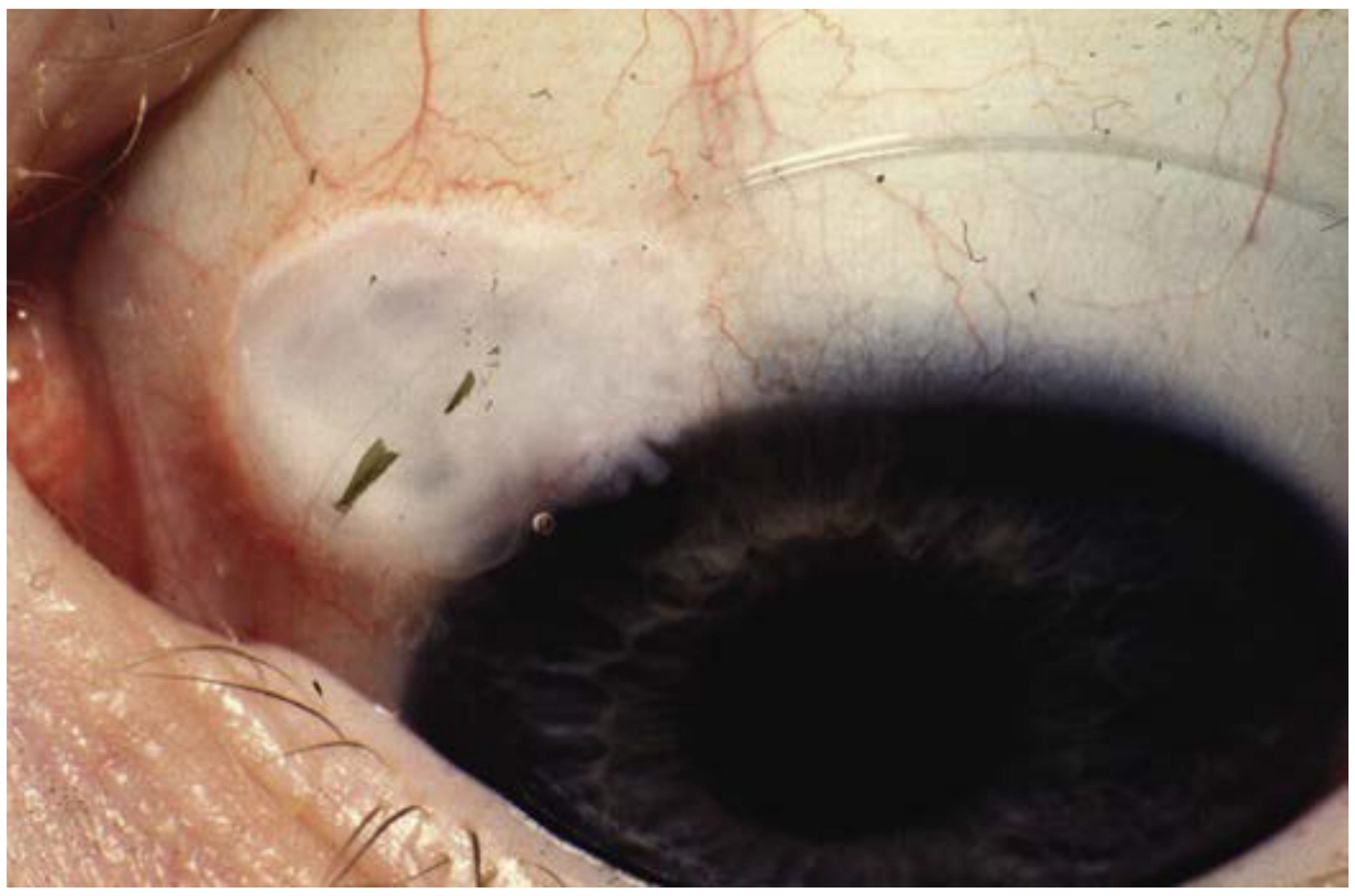

Fig. 29.5 A leaking drainage bleb fitted with a large-diameter hydrogel lens in an attempt to form a seal. Even at 20 mm diameter, the lens was not large enough to cover the bleb fully, but was just functional as the perforation of the bleb was in proximity to the limbus. (Courtesy of Daniel Ehrlich.)

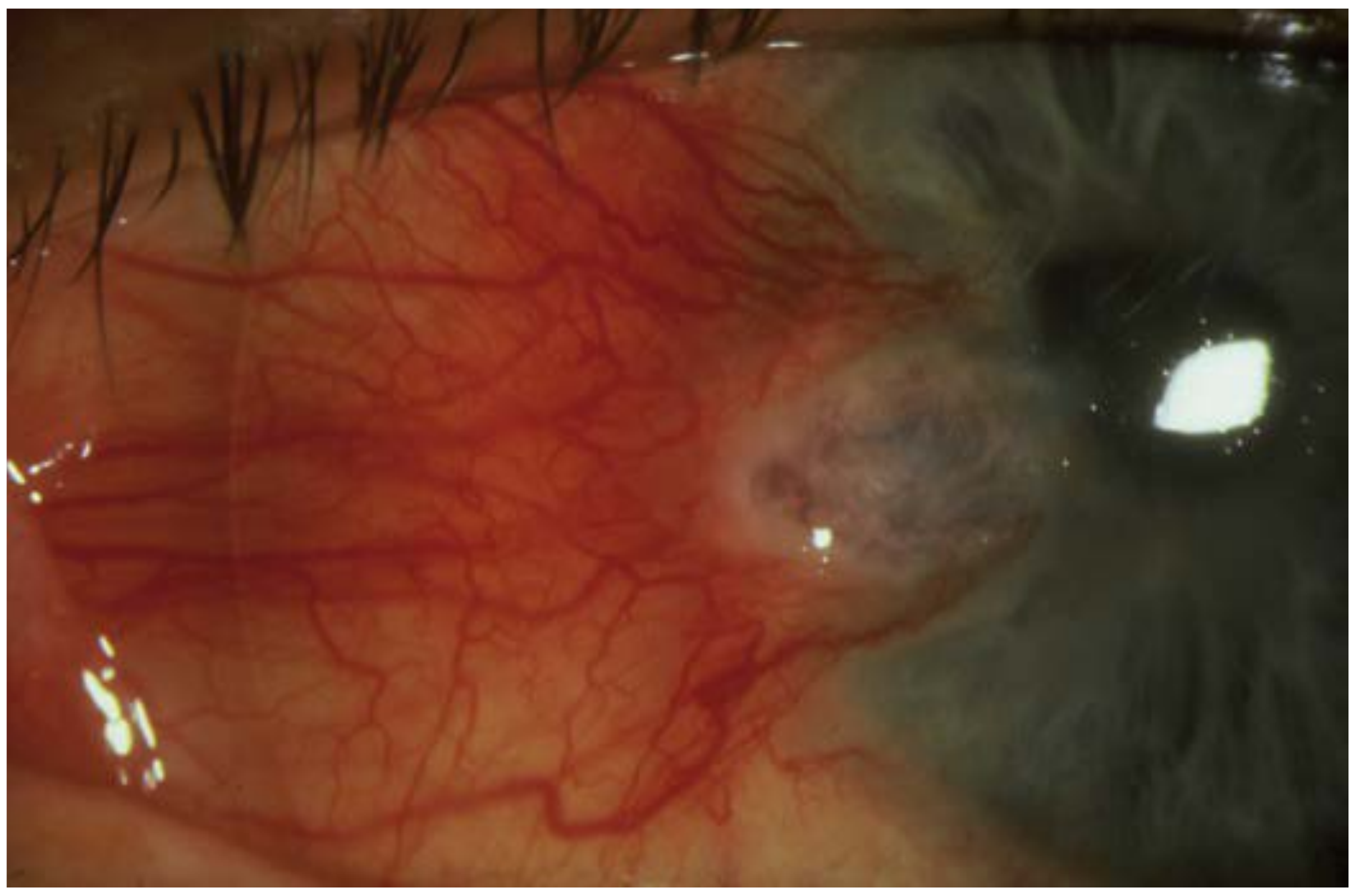

Fig. 29.6 Corneal melting after perforating trauma with loss of sutures and wound leakage. The cornea was sealed with histoacryl tissue glue and fitted with a large-diameter (20.5 mm) high-water-content (76.5%) soft bandage lens. The glue spontaneously dislodged after 10 days and the bandage lens was removed. (Courtesy of Jan Kok, Bausch & Lomb Image Library.)

renders the normally hydrophilic ocular surface hydrophobic – a precorneal tear reservoir can be created with the aid of a scleral lens with full corneal and limbal clearance. A sealed lens may be needed in order to retain the reservoir, in which case a gas-permeable material is used and the lens is filled with normal saline before being placed on the eye (see Chapter 21).

FOLLOWING TRAUMA OR SURGERY

Persistent or recurrent epithelial defects may heal more rapidly following the application of a soft (hydrogel or silicone hydrogel) bandage lens. A small aqueous leak following surgery (Fig. 29.5) or trauma (Fig. 29.6) can often be sealed with such a lens; if the anterior chamber is shallow or absent then a slightly flat lens will be needed, and this will have to be changed for a steeper lens as the chamber reforms and the cornea steepens.

Shoham et al. (2000) have successfully used a custom-made 17.5 mm diameter 78% water content bandage lens to arrest leakage from trabeculectomy filtration blebs. Corneal transplant problems such as loosening sutures or slippage of the donor disc are usually best dealt with by further surgery, for example suture removal and/or resuturing. In such situations, contact lenses are unlikely to have more than a temporary role (e.g. the relief of discomfort while arrangements are made for surgical intervention).

FOLLOWING SPONTANEOUS PERFORATION

Management of corneal perforation from acute hydrops may be attempted with bandage contact lens placement. A flat anterior chamber may reform within 24 hours (Yeh and Smith, 2008). Forooghian et al. (2006) reported on their success with a bandage lens following perforation in a patient with pellucid marginal degeneration.

Lens Types

It should be recalled that all types of contact lens have therapeutic uses.

SOFT HYDROGEL AND SILICONE HYDROGEL LENSES

When considering the fitting of a bandage lens, it is necessary to define or predict its probable pattern of use. The relevant considerations are:

- whether extended wear is necessary
- whether the patient (or, failing the patient, a relative or friend) can be taught to handle, or at least to remove, the lens
- the likely duration of therapeutic lens management
- whether the patient lives within practical travelling distance of the clinic or hospital
- whether the necessary topical medications are available unpreserved
- whether the risks of hypoxia, mechanical trauma and infection are outweighed by the perceived benefits of therapeutic lens wear.

In the past, clinics may have kept sets of bandage lenses – custom-made from high-water-content materials – in various radii and diameters. These were superseded by commercially available frequent-replacement hydrogel lenses (Rubinstein, 1995; Bouchard and Trimble, 1996; Srur and Dattas, 1997), which in turn, have largely been replaced by lenses in silicone hydrogel materials.

Silicone hydrogel lenses have an important therapeutic role because of their very high gas permeability, which minimizes the induced hypoxic and hypercapnic stress (Lim et al., 2001). Their relatively low water content is an advantage where hydration of the lens by the tear film is problematic, as occurs in aqueous tear deficiency. Comparison studies have been carried out between hydrogel and silicone hydrogel lenses in some therapeutic applications. For example, silicone hydrogel lenses have been shown to be a safe and effective alternative to conventional contact lenses for the treatment of bullous keratopathy (Lim and Vogt, 2006).

Silicone hydrogel lenses are widely used following photorefractive keratectomy (PRK) and laser-assisted subepithelial keratomileusis (LASEK) (Chapter 30). In one study, the corneal

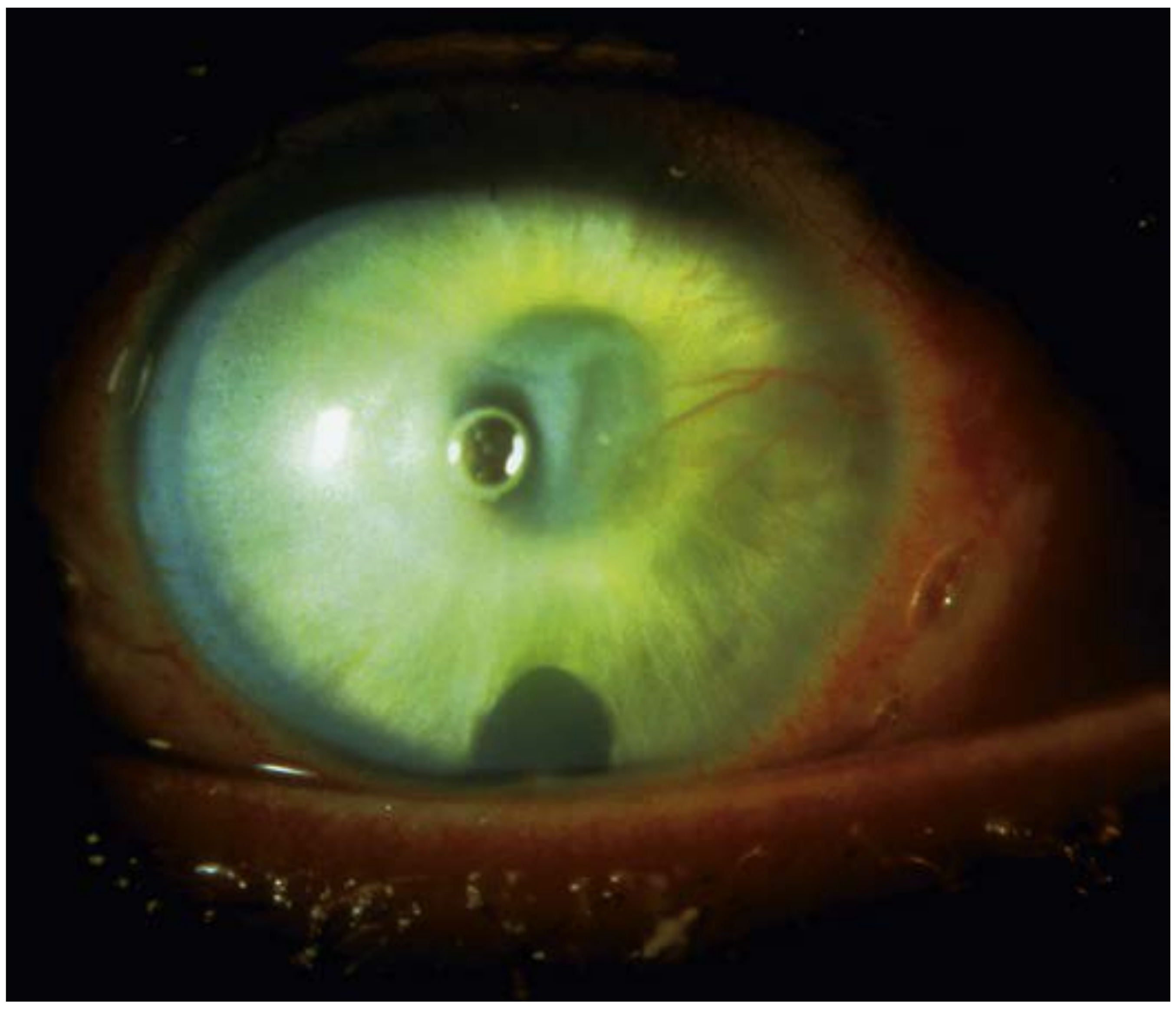

Fig. 29.7 A large (20.5 mm diameter) soft bandage lens fitted to relieve pain in a 27-year-old man with Marfan's syndrome following ethylenediamine tetraacetic acid (EDTA) treatment. After numerous eye operations (cataract extraction, ablatio retinae, vitreous oil procedures), a painful band keratopathy formed, and a trophic ulcer was present. (Courtesy of W. Vreugdenhil, Bausch & Lomb Image Library.)

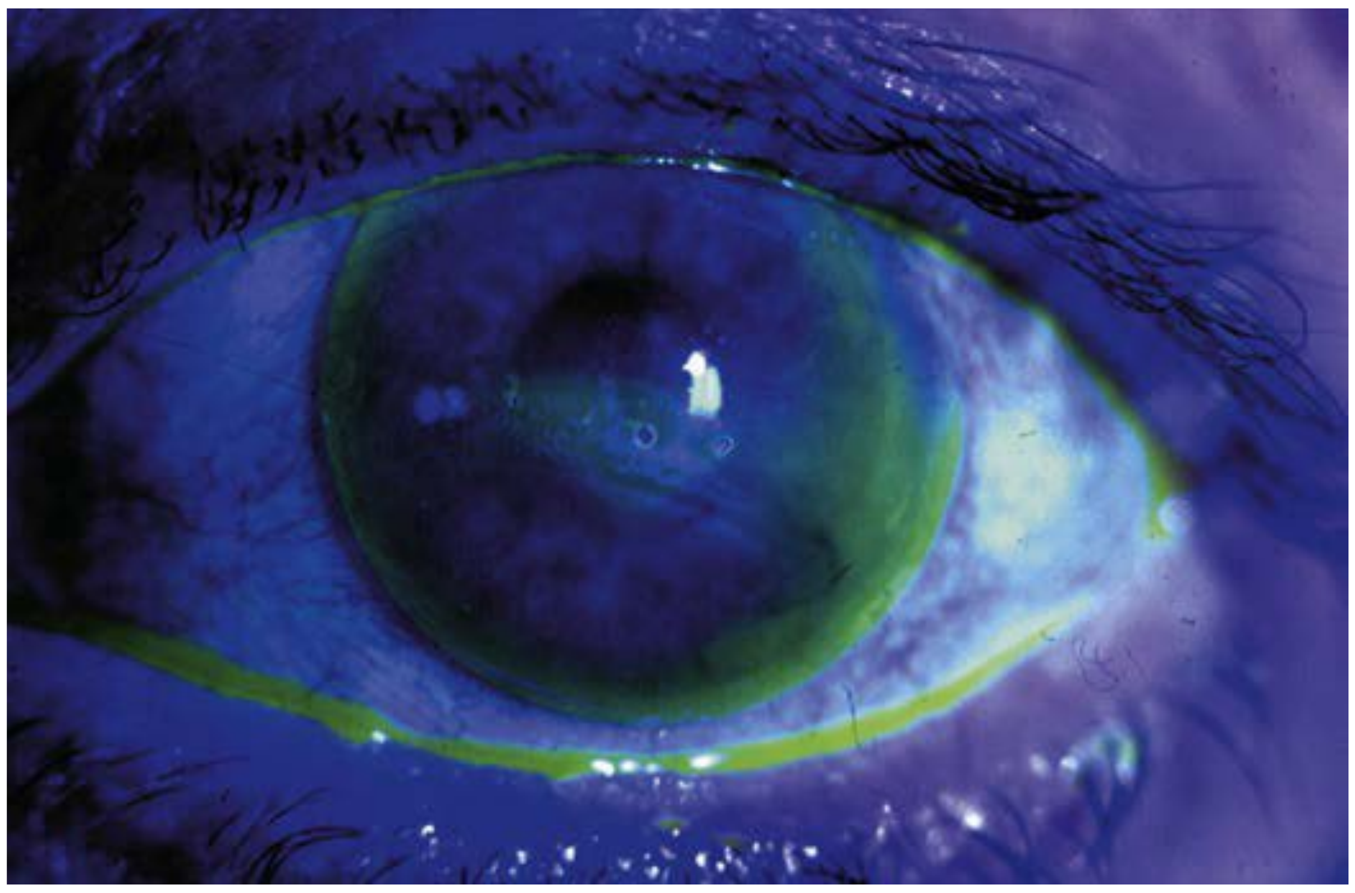

Fig. 29.8 A large limbal diameter rigid lens has been fitted to protect a neurotrophic corneal lesion in the early stages of the healing process. (Courtesy of Ken Pullum.)

epithelial status was statistically better in the eyes with a silicone hydrogel bandage contact lens 5 days after surgery compared with when a hydrogel lens was worn (Gil-Cazorla et al., 2008a). Studies evaluating the relative performance of different silicone hydrogel lenses have shown little difference between them, except in terms of comfort (Gil-Cazorla et al., 2008b; Mukherjee et al., 2015).

When fitting any soft lens, it is important for the lens to overlap all areas requiring cover, and to aim for a little movement on blinking. There must be no compression of the limbal vessels (Fig. 29.7).

RIGID LENSES

Rigid lenses are frequently used for a combination of optical and therapeutic indications. Though they are usually smaller in diameter than the cornea, they may provide enough cover to protect the cornea from abnormal lashes, keratinized lid margins and other hostile factors. Sometimes lenses of larger diameters are used (Fig. 29.8).

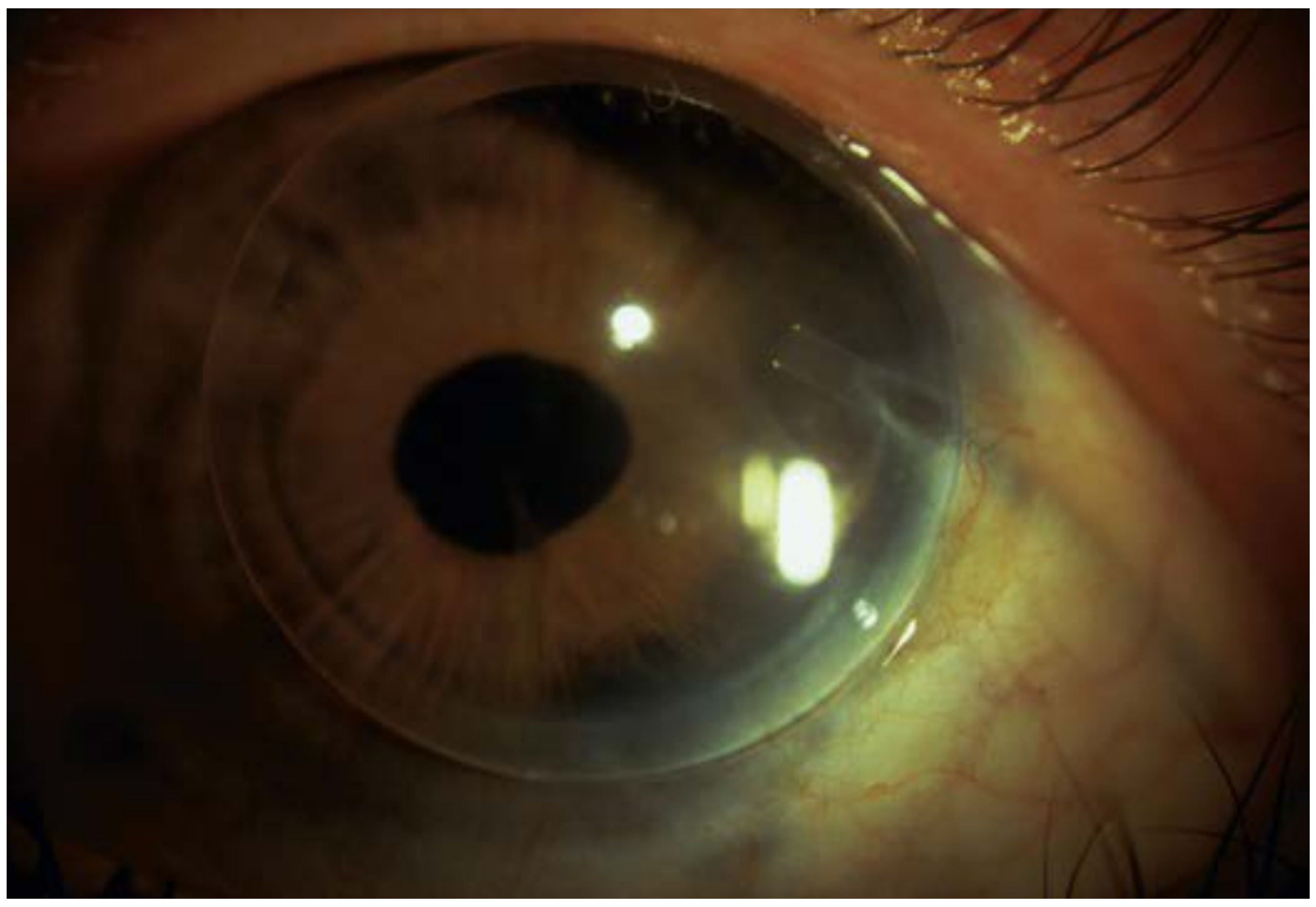

Fig. 29.9 Rigid lens fitted to a buphthalmic eye. (Courtesy of W. Vreugdenhil, Bausch & Lomb Image Library.)

Fig. 29.9 shows a rigid lens that has been fitted to a highly myopic (−10.00 D) buphthalmic eye of a 29-year-old male; a drainage tube can be seen entering the anterior chamber from the right of the image.

In ectatic conditions, such as keratoconus, keratoglobus and pellucid marginal degeneration (together constituting primary corneal ectasia), the cornea may become highly astigmatic, necessitating the fitting of a rigid bitoric lens. Such a case is demonstrated in Fig. 29.10. A deep crescent-shaped corneal scar extends from the 4 o'clock to the 8 o'clock position. The scar is present at the level of Descemet's membrane and deep stroma, in the upper region of the zone of corneal thinning (Fig. 29.10A). The vertically oval image of the perfectly circular Placido rings (Fig. 29.10B) indicates against-the-rule astigmatism, and the closeness of the inferior rings indicates a very steep corneal profile due to ectatic bulging of the zone of corneal thinning. The bitoric rigid lens (Fig. 29.10C) affords good vision. The fluorescein pattern is typical of such conditions (Fig. 29.10D); the inferior ectatic corneal protrusion can be seen to bear against the lens.

SCLERAL LENSES

Scleral lenses have a host of therapeutic roles (Tan et al., 1995; Romero-Rangel et al., 2000; Pullum and Buckley, 2007). Their advantages include the following:

- There need be no corneal contact whatsoever.
- Any eye shape can be fitted.
- Complete protection of the cornea and bulbar conjunctiva is provided.
- Sealed fits are possible, using gas-permeable materials, which simplifies the fitting process and minimizes 'settling back'.
- Using gas-permeable materials, overnight wear is possible.

At one time the fitting, and especially the ventilation, of scleral lenses required much practical experience. With the advent of gas-permeable scleral lenses, however, sealed fits have become the norm and less skill is required. So many medical and therapeutic indications have demonstrated that it can

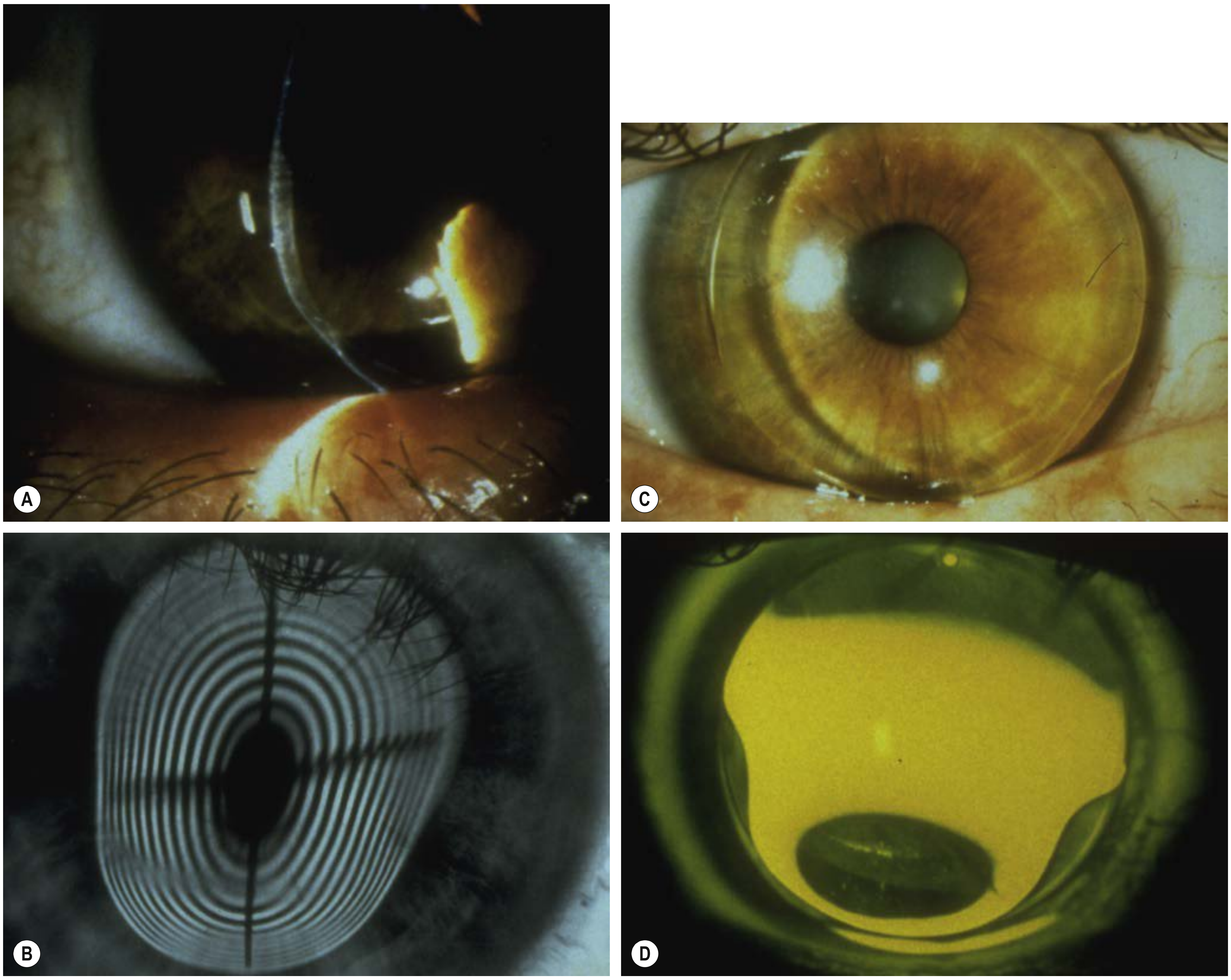

Fig. 29.10 Bitoric rigid lens fitting in pellucid marginal degeneration. (A) Cornea viewed in optic section. (B) Placido image of cornea. (C) Bitoric rigid lens. (D) Fluorescein pattern indicates bearing of the inferior ectatic corneal zone against the lens (see text). (Courtesy of C. van Mil, Bausch & Lomb Image Library.)

now be regarded as essential for specialist contact lens clinics to be able to fit scleral lenses (see Chapter 21).

Concurrent Medication

Unpreserved unit-dose eye drops are indicated for concurrent use with soft lenses. Preserved eye drops are rarely used in this situation, because of concerns that preservatives such as benzalkonium chloride can accumulate in the lens and be toxic to the corneal epithelium. This effect is usually of no clinical importance when disposable lenses are used for short periods. All topical drugs may be used with rigid lenses – both corneal and scleral. It is not known whether drugs achieve suitable concentrations in the ocular tissues when sealed scleral lenses are being worn. Ointment preparations and oily drops should not be used concurrently with contact lenses.

Drug Delivery

Using contact lenses for ophthalmic drug delivery is a concept that is becoming increasingly popular, owing to their unique advantages like extended wear and more than 50% bioavailability. To achieve controlled and sustained drug delivery from soft contact lenses, researchers are working on various systems such as polymeric nanoparticles, microemulsion, micelle, liposomes, and the use of vitamin E. Numerous techniques are being employed to effect drug delivery, such as simple lens soaking, novel materials, molecular imprinting, entrapment of drug-laden colloidal nanoparticles, diffusion barriers, drug plate/film, ion ligand polymeric systems, surface modification, layering and supercritical fluid technology (Maulvi et al., 2016).

Although sustained drug delivery can be achieved using soft lenses, critical properties such as water content, tensile strength, ion permeability, transparency and oxygen permeability may be altered, which has the potential to adversely impact contact lens performance. Many issues are still unresolved – such as drug stability during processing/fabrication (drug integrity test), zero-order release kinetics (prevention of burst release), drug release during monomer extraction step after fabrication (to remove unreacted monomers), protein adherence, drug release during storage in packaging solution, and limited shelf life (Maulvi et al., 2016).

Such techniques have been used in the delivery of anti-glaucoma drugs, antibiotics, antiviral agents, epidermal growth factor and fibronectin (LeBourlais et al., 1998). Daily disposable lenses offer the advantage of applying a new drug delivery dose each day, or as desired (Bajgrowicz et al., 2015).

Complications

The adverse effects of contact lenses used therapeutically are similar to those with lenses used generally (see Chapter 40), although the diseased or injured eye may be especially at risk. Complications of particular concern in therapeutic contact lens prescribing include hypoxia with or without neovascularization, sterile corneal infiltrates and suppurative keratitis. Saini et al. (2013) reported that even prophylactic antibiotic use did not eliminate the risk for microbial keratitis with silicone hydrogel bandage lens use in patients with chronic ocular surface disease.

Careful follow-up is vital after the fitting of a lens for a therapeutic indication, and there is as yet no reason to vary the convention of examining the eye on the day after fitting and not more than 1 week after that. If unplanned-replacement lenses are used, spoilation may be observed to occur more quickly than with healthy eyes. Any change in the comfort or vision of the patient may be of great significance and instruction should be given to the patient to remove the lens in such circumstances, and to return to the clinic as an emergency if not rapidly relieved of the new symptoms.

Conclusion

One aim of this chapter was to dispel the misapprehension that the term 'therapeutic contact lens' is synonymous with a soft plano 'bandage' lens. All types of contact lenses have a potentially important therapeutic role to play in the relief of pain or discomfort and in facilitating the healing of injured or diseased ocular tissue.

ACKNOWLEDGEMENTS

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Access the complete references list online at http://www.expertconsult.com.

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30

Post-refractive Surgery

SUZANNE E EFRON

Introduction

Fifty years of evolution in refractive surgery procedures has left in its wake a large group of patients with suboptimal visual results. Today, these patients are faced with three corrective options – glasses, contact lenses or further refractive surgery. For some of these individuals, where there is induced anisometropia, restoration of binocular vision may be achieved with contact lenses. Where there is induced irregular astigmatism, contact lenses, and in particular rigid lenses, may provide the only option for visual rehabilitation (Alió et al., 2002). Rigid lenses are able to correct the residual refractive error and reduce the elevated total higher-order aberrations to more normal levels (Gemoules and Morris, 2007).

Types of Refractive Surgery

The number of different refractive surgical procedures continues to grow. Previous and current procedures are listed in Table 30.1. Each of these procedures modifies the corneal surface in a unique way, necessitating a rethinking of traditional lens designs and fitting techniques for optimal contact lens performance. Laser-assisted in situ keratomileusis (LASIK) continues to be the dominant procedure for preoperative refractions from −8.00 to +3.00 D (Duffey and Leaming, 2005).

Contact Lens Fitting Following Photorefractive Procedures

There are three main indications for fitting contact lenses following photorefractive procedures:

- bandage lenses in the immediate postoperative period following photorefractive keratotomy (PRK) and laser-assisted sub-epithelial keratomileusis (LASEK), where the epithelium is removed during the procedure
- for ametropia following under- or overcorrection
- to correct irregular corneal astigmatism, which may have been pre-existing, induced during surgery, or due to post-surgical ectasia.

TISSUE ABLATION AND CORNEAL TOPOGRAPHY

PRK, LASIK and LASEK are all tissue subtraction procedures and the amount of corneal tissue removed will play an important role in the post-surgical management of the patient.

Tissue removal is determined by the Munnerlyn formula:

$$\text{Depth of ablation} = [(\text{optic zone diameter})^2 \times (\text{refractive error})]/3$$

Example of myopia correction:
Ablation diameter (optical zone diameter) = 6.0 mm
Optical zone squared (6.0 × 6.0) = 36
Multiplied by the desired correction (−6.00) = 216
Divided by 3 = 72
Thus, depth of the ablation = 72 µm.

Irregular astigmatism is a relatively rare finding after either PRK or LASIK. However, it may be induced by the creation of a suboptimal lamellar flap – too thin, irregular, bisected, buttonholed or a free flap, or be due to postoperative ectasia. Flap striae are an other important and often underrecognized cause (Polack and Polack, 2003). Irregular astigmatism can also arise from a decentred ablation. Patients are often left with varying degrees of uncorrected myopia due to the eccentric position of the treatment zone away from the visual axis. Viewing through the edge of the ablation frequently results in a loss of best corrected visual acuity (BCVA), monocular diplopia and ghosting of distance images, especially under scotopic conditions. The severity of symptoms often correlates with the size of the pupil. A decentred ablation with a large 6–7 mm pupil will produce more serious visual complaints than does a similarly displaced ablation over a small 3–4 mm pupil. Soft contact lenses rarely provide adequate optical correction in this small subset of

TABLE 30.1 Types of Refractive Surgery

Incisional	Laser	Other
Radial keratotomy (RK) Astigmatic keratotomy (AK) Limbal-relaxing incisions (LRI) Corneal-relaxing incisions (CRI)	Photorefractive keratectomy (PRK) Laser-assisted in situ keratomileusis (LASIK) Laser-assisted sub-epithelial keratomileusis (LASEK) Laser thermokeratoplasty (LTK) Small-incision lenticule extraction (SMILE) Femtosecond laser-assisted in situ keratomileusis (Femto-LASIK) Femtosecond laser lenticule extraction (FLEx)	Keratophakia Keratomileusis Epikeratoplasty Thermokeratoplasty Conductive keratoplasty (CK) Automated lamellar keratoplasty Intrastromal corneal ring segments (ICRS)

patients. Optimal visual performance usually requires the use of a rigid lens design.

Refractive surgery techniques are moving forward with the introduction of femtosecond lasers. These create LASIK flaps with better accuracy, uniformity and predictability than do mechanical microkeratomes (Chen and Manche, 2016). The higher-frequency femtosecond platforms elicit less inflammation, also producing better visual outcomes. Small-incision lenticule extraction (SMILE) is another procedure made possible by femtosecond lasers and it achieves similar safety, efficacy and predictability to LASIK with greater preservation of corneal nerves and biomechanical strength (Zhang et al., 2016). It is to be hoped that the need for post-refractive surgery contact lens fitting may be reduced in future.

CORNEAL SENSITIVITY AND DRY-EYE SYMPTOMS

Practitioners need to be aware of the level of corneal sensitivity following laser refractive surgery if contact lenses are to be fitted. The recovery of corneal sensitivity following PRK and LASIK was measured by Pérez-Santonja et al. (1999). Following PRK, a decrease in central corneal sensitivity was noted at 1 week, but sensitivity had nearly recovered at 1 month after surgery. Following LASIK, there was a deep decrease in central corneal sensitivity at both 1 week and 1 month after surgery. Corneal sensitivity values were found to be similar after 6 months – a finding in agreement with that of Benitez-del-Castillo et al. (2001). Darwish et al. (2007) examined subbasal nerve regeneration after LASEK using confocal microscopy and found corneal sensitivity had returned to normal levels after 3 months; however, subbasal nerves that were injured by LASEK had not returned to preoperative levels by 6 months after surgery.

Patients frequently experience dry-eye symptoms after LASIK; however, the mechanisms that lead to these changes are not well understood. Tear film dysfunction has obvious implications if contact lenses are required after surgery. Yu et al. (2000) followed post-LASIK patients for 1 month and observed increased dry-eye symptoms, and reduced Schirmer test results, basal tear secretion and tear break-up time during this period. Benitez-del-Castillo et al. (2001) reported that tear secretion was reduced for a period of 9 months following LASIK surgery. After LASEK, Darwish et al. (2007) found tear break-up time had decreased significantly and had not returned to the preoperative level by 6 months after surgery.

SOFT LENSES

With myopic ablations, the mid-peripheral cornea (beyond the central 6.0–7.0 mm) remains unchanged. Therefore, the major concern in fitting soft or rigid contact lenses is the relative difference between the flatter central cornea and the steeper (normal) mid-peripheral cornea. This difference creates few problems for patients who had low to moderate myopia prior to surgery. In such cases, the small amount of tissue ablated does not noticeably affect the contact lens fit or the on-eye lens dynamics. Most of the currently available daily disposable or frequent-replacement soft lenses are viable options for the post-laser correction. However, after surgery a complex relationship exists between visual acuity, defocus (refractive error), diffraction and optical aberrations. The loss of postoperative central corneal asphericity can result in a form of spherical aberration (Hong and Thibos, 2000). For patients with large pupils this can be symptomatic. Improved optical correction can be achieved with soft lens designs that incorporate aberration-correcting anterior aspheric optics.

Bandage Lenses

Bandage lenses are used in the immediate postoperative period to relieve pain and to assist in re-epithelization following PRK and LASEK. These procedures involve removal of the corneal epithelium. The corneal surface needs between 2 and 4 days to regenerate, so lenses are typically worn continuously for 3–5 days following surgery. Managing the wound-healing response is critical for a successful outcome to ensure re-epithelization occurs quickly, thereby reducing stromal haze (Tomás-Juan et al., 2015). This is best achieved with lenses of high Dk/t, for increased corneal oxygenation.

Many studies have been carried out to assess the relative benefits of different silicone hydrogel lens materials and designs when used as bandage lenses (Gil-Cazorla et al., 2008; Taylor et al., 2014; Mukherjee et al., 2015). All found no major clinical difference between the lenses, although patients reported greater comfort with senofilcon A lenses. Mukherjee et al. (2015) concluded that factors other than oxygen permeability affect pain and epithelial healing.

RIGID LENS DESIGNS

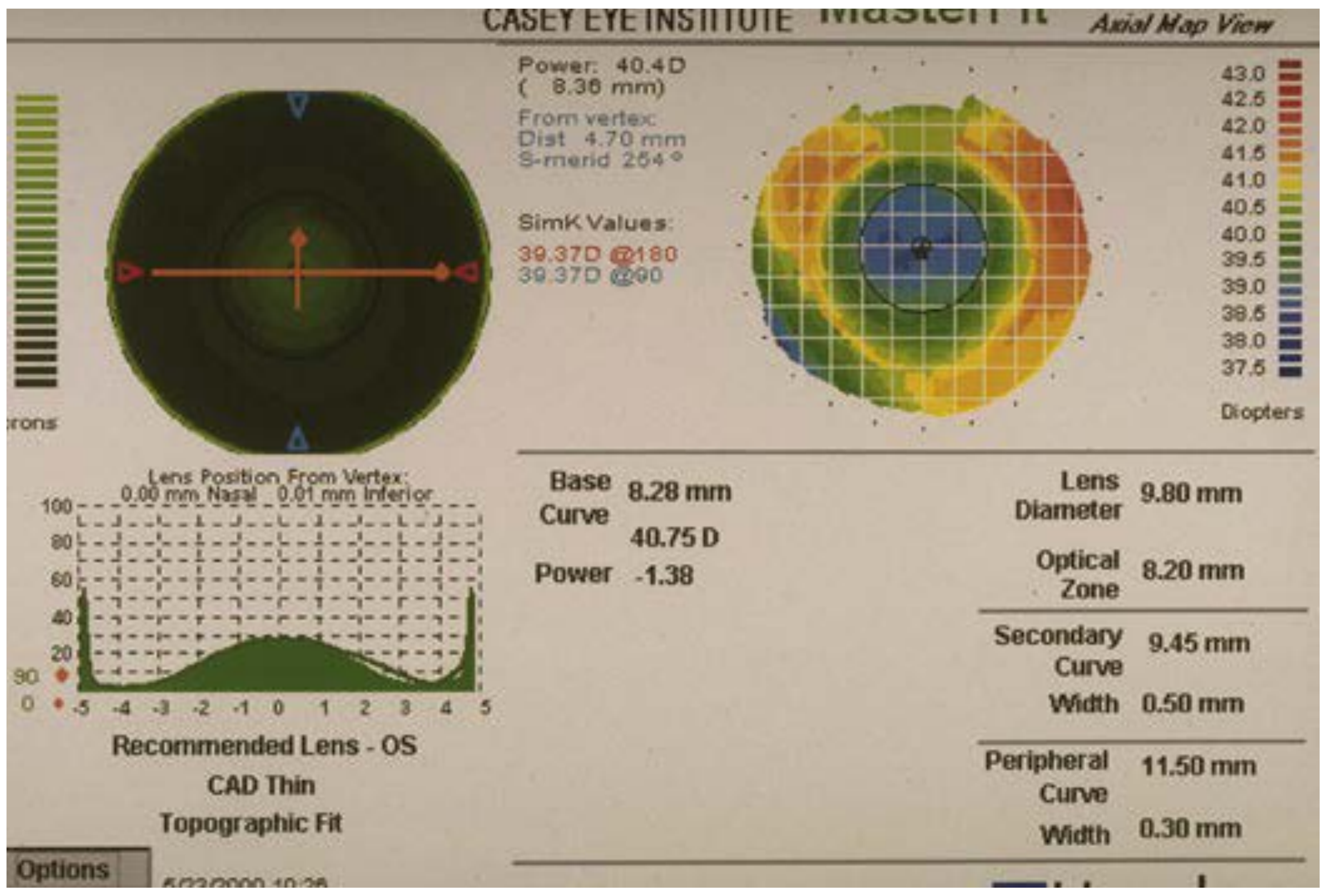
With both PRK and LASIK, rigid lens fitting is best delayed until approximately 8–12 weeks after surgery. At this point, the refraction and topography have stabilized. At 3 months post-surgery, the integrity of the flap interface is usually sufficient to withstand the minor trauma associated with lens insertion and removal, as well as the normal on-eye movement that occurs with blinking.

Many patients who have undergone PRK or LASIK can be successfully fitted with traditional spherical or aspheric rigid lenses. However, Lim et al. (1999) suggest that patients fitted with rigid lenses can display mild to moderate lens instability and decentration after PRK. As with soft lens fitting, the extent of tissue removal will influence the ease of fitting. For example, a patient with a preoperative refractive error of −4.00 D might end up postoperatively −1.00 D undercorrected. The 3.00 D myopic reduction was produced by an ablation of approximately 36 μm of tissue (less than the thickness of the human epithelium). The minimal difference between the central and mid-peripheral cornea creates few fitting and/or optical problems for a traditional rigid lens design. These individuals are often best fitted with a BOZR designed to align the mid-peripheral corneal topography 4.0 mm from the centre of the cornea (Fig. 30.1).

In contrast, the corneal shape following hyperopic laser correction is steeper, with a positive value for eccentricity often exceeding 0.5–0.7 (Gruenauer-Kloevekorn et al., 2006). It may be necessary to consider a lens design usually reserved for keratoconus.

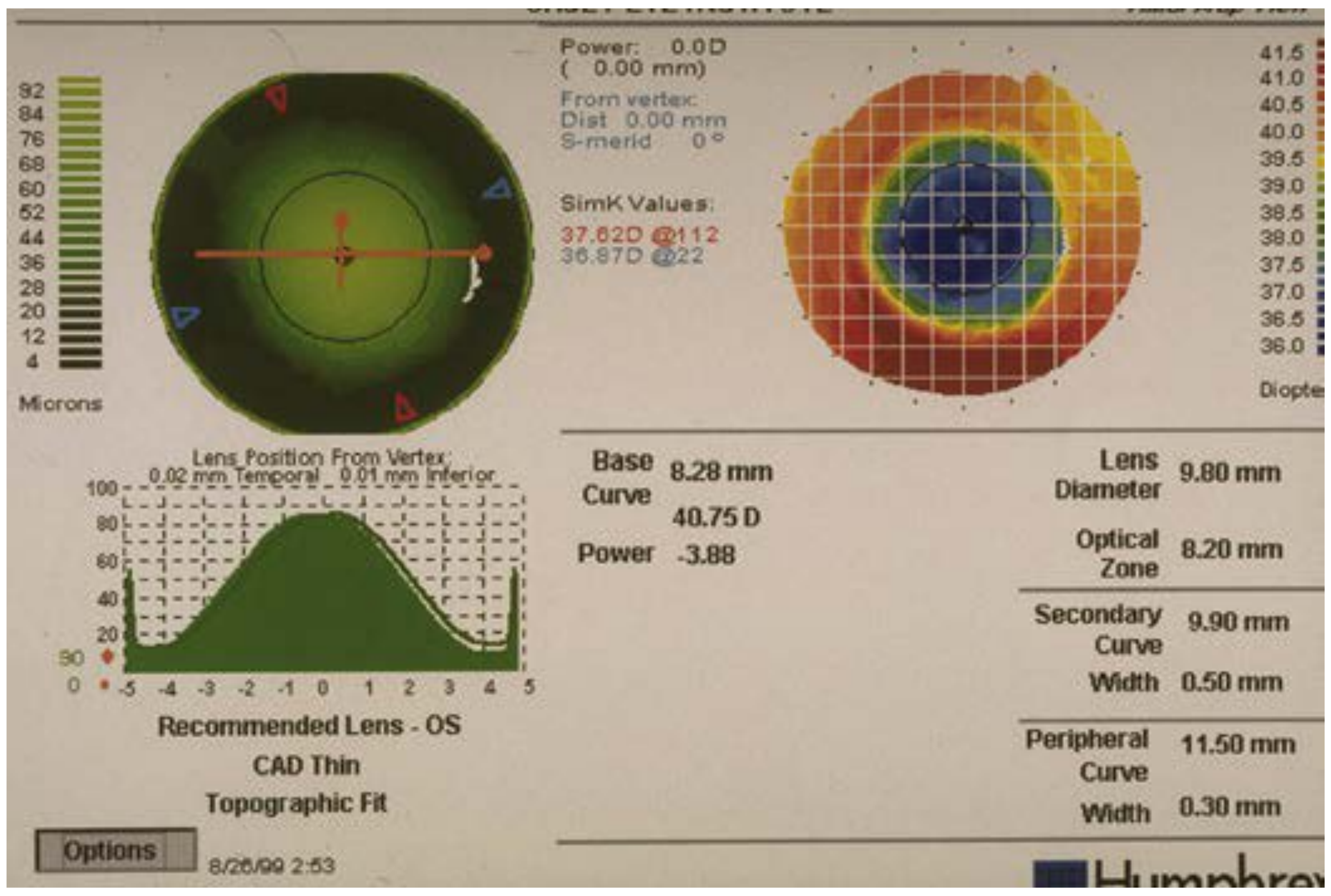
Reverse-geometry Rigid Lens Designs

When considering a patient with a higher preoperative refractive error, for example −10.00 D, who might end up postoperatively −1.00 D, the −9.00 D myopic reduction requires the removal of approximately 110 μm of corneal tissue. In this case, the difference between the central and mid-peripheral cornea is such that a traditional rigid lens (designed to align with the mid-peripheral cornea)



Power: 40.4D
(8.36 mm)
From vertex:
Dist 4.70 mm
S-merid 264°
SimK Values:
39.37D @180
39.37D @90
Base Curve 8.28 mm
40.75 D
Power -1.38
Recommended Lens - OS
CAD Thin
Topographic Fit
Lens Diameter 9.80 mm
Optical Zone 8.20 mm
Secondary Curve 9.45 mm
Width 0.50 mm
Peripheral Curve 11.50 mm
Width 0.30 mm

Fig. 30.1 Simulated fluorescein pattern of a post-laser-assisted in situ keratomileusis (LASIK) eye with a −3.00 D correction.



Power: 0.0D
(0.00 mm)
From vertex:
Dist 0.00 mm
S-merid 0°
SimK Values:
37.62D @112
36.87D @22
Base Curve 8.28 mm
40.75 D
Power -3.88
Recommended Lens - OS
CAD Thin
Topographic Fit
8/26/99 2:53
Lens Diameter 9.80 mm
Optical Zone 8.20 mm
Secondary Curve 9.90 mm
Width 0.50 mm
Peripheral Curve 11.50 mm
Width 0.30 mm

Fig. 30.2 Simulated fluorescein pattern of a post-laser-assisted in situ keratomileusis (LASIK) eye with a −9.00 D correction.

may exhibit excessive apical clearance (Fig. 30.2). The subsequent large volume of tears centrally can result in unstable optics and trapped bubbles can form beneath the centre of the lens.

In such situations, patients may be best managed with reverse-geometry lens designs (Lim et al., 2000; Martin and Rodriguez, 2005) (Fig. 30.3). A standard rigid design mimics the prolate shape of the normal, unoperated cornea, which is steeper in the centre than the periphery. The reverse-geometry design more closely parallels the post-refractive surgery topography (of a previously myopic eye) by incorporating a flat central radius of curvature with a steeper mid-peripheral design (see Fig. 30.3). This creates a plateau configuration on the posterior lens surface, which dramatically decreases the volume of tear fluid present beneath the central portion of the lens (Szczotka, 1998).

SCLERAL LENSES

Scleral or miniscleral lenses are well suited to therapeutic correction of eyes following refractive surgery, even in patients who have previously been intolerant to other contact lenses (Parminder and Jacobs, 2015). They are indicated for:

- refractive instability – any diurnal fluctuations in refraction are minimized as they act at a cornea–saline interface not at a cornea–air interface

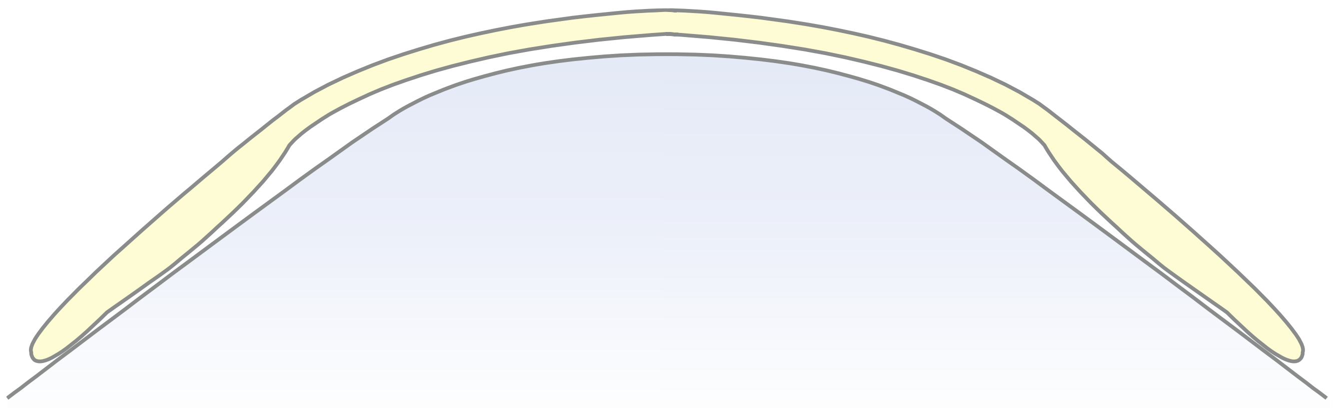


Fig. 30.3 Reverse-geometry lens design.

- irregular astigmatism and keratectasia – the fluid reservoir behind the lens acts to neutralize optical irregularities from the corneal surface
- dry eye and postoperative pain syndromes – the fluid reservoir appears to ameliorate pain caused by trauma to the corneal nerves during surgery (Levitt et al., 2015).

The fit of the scleral lens is independent of corneal contour and issues of poor centration and lens instability are minimized (see Chapters 21 and 26).

Contact Lens Fitting Following Radial Keratotomy

Radial keratotomy (RK) has largely been phased out in favour of more sophisticated and predictable laser surgical procedures. However, an understanding of the difficulties in fitting the post-RK cornea is still required for the contact lens management of these patients as it poses far greater challenges than those encountered after photorefractive keratectomy.

Contact lens fitting differs between laser and incisional procedures. After RK:

- There are greater changes in the mid-peripheral cornea.
- Fewer soft contact lens designs can be used owing to the presence of perilimbal incisions.
- The cornea may have elevated mid-peripheral pivot points secondary to incisional wound healing. These areas are the major cause of rigid lens decentration.
- There is more diurnal fluctuation in visual acuity because of the instability of the peripheral cornea. This is especially important if soft contact lenses are used.

Astin (1991) warns that the cornea is malleable and prone to warpage during a period of up to 3 months following RK and advises that one should not carry out lens fitting during this period unless it is medically necessary. A hyperopic shift in refraction can continue for 10 years after surgery (Waring et al., 1994; Charpentier et al., 1998).

CORNEAL TOPOGRAPHY

When radial incisions are placed into the mid-peripheral cornea, the wounds gape open under the force of the intraocular pressure and stresses form within the corneal tissues (Fig. 30.4). The gaping incisions are first filled with an epithelial plug, which is eventually replaced by a permanent wedge of fibroplastic scar tissue (Fig. 30.5). This results in an overall increase in corneal surface area, although the corneal diameter remains unchanged.

There is a common misconception that the mid-peripheral cornea steepens following RK. However, as the anterior cornea displaces to accommodate the gaping incisions, virtually the entire cornea from limbus to limbus flattens. The flattening effect is simply greater in the central cornea than in the periphery, resulting in the false impression of mid-peripheral steepening.

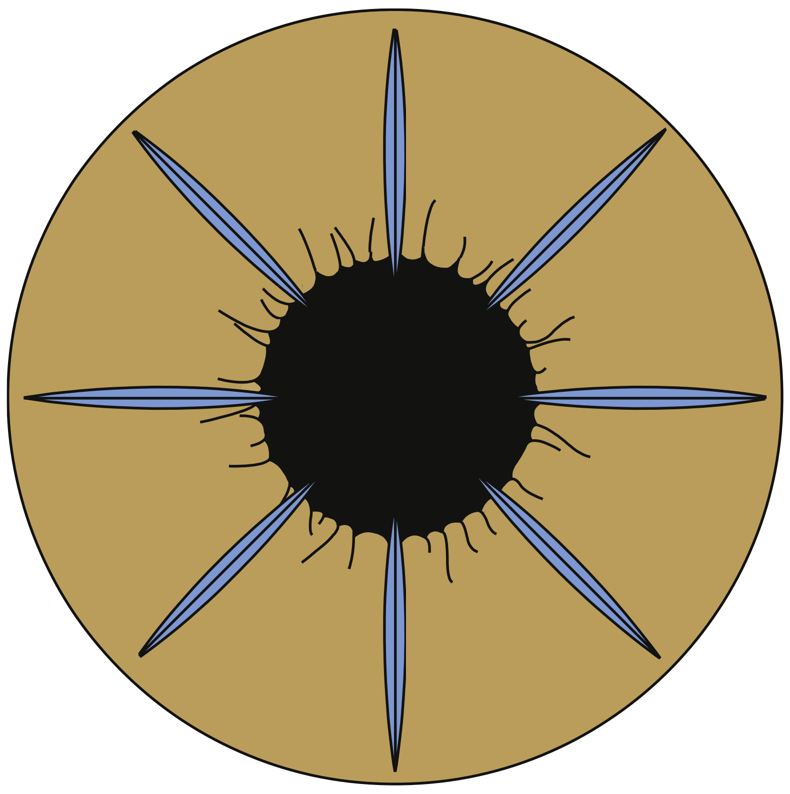


Fig. 30.4 Wound gape created by symmetrically placed radial incisions.

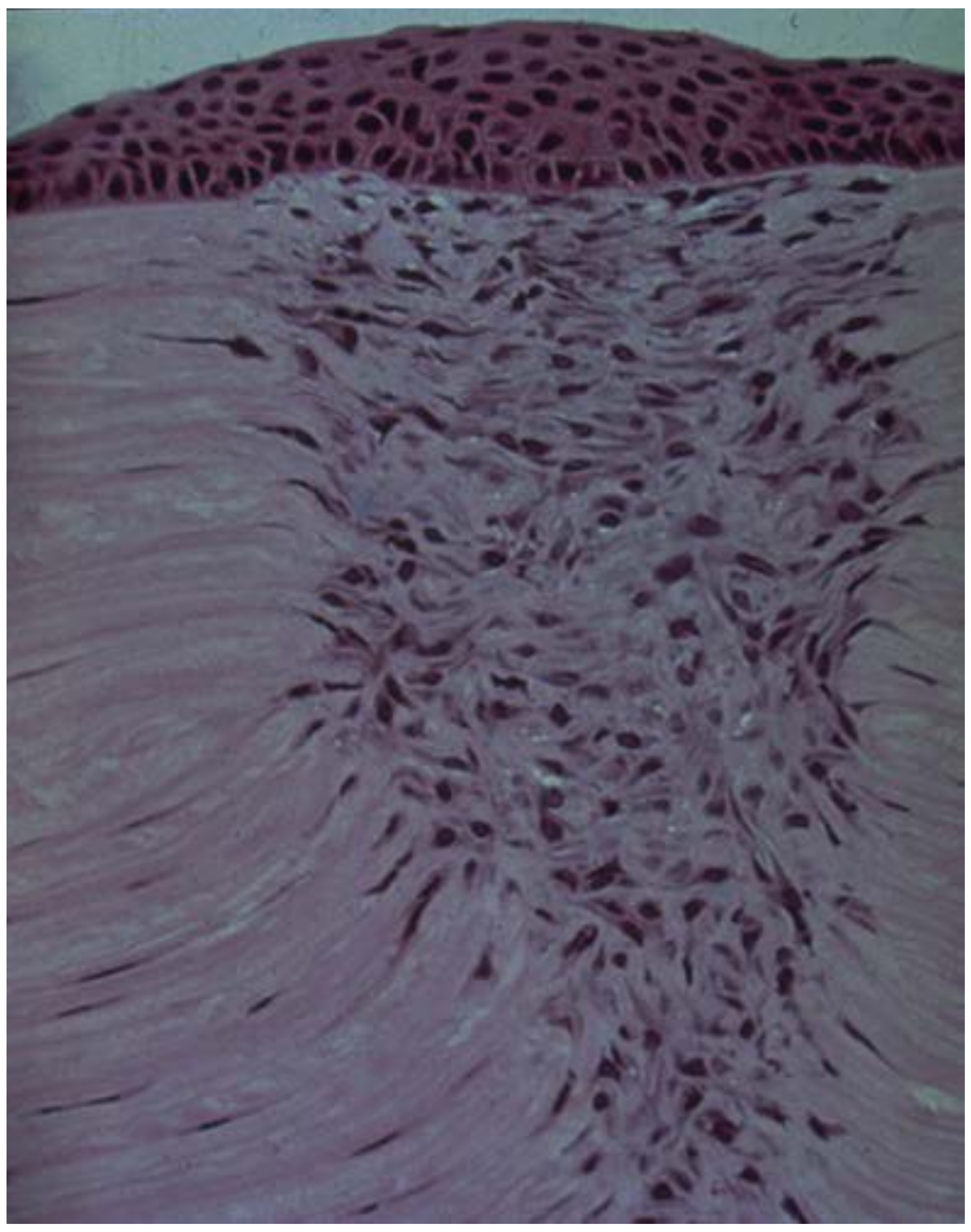


Fig. 30.5 Wedge-shaped fibroplastic scar in a healed radial incision (cat eye).

The degree of wound gape and the resultant amount of corneal flattening are dictated by a number of surgical and biological factors, including the following:

- the number, depth and length of the incisions
- intraocular pressure forces
- stresses and biochemical properties within the corneal tissue
- patient age at the time of surgery
- individual wound-healing responses.

SOFT LENSES

In principle, the fitting of a soft contact lens to a cornea that has undergone RK is very similar to fitting a normal cornea. The BOZR will usually need to be approximately 0.5 mm greater than the flattest keratometry reading. However, in most cases a BOZR of greater than 9 mm will be required to achieve satisfactory alignment with the post-RK cornea, therefore the soft lens will need to be custom made. Disposable lenses will be a possibility only when the amount of central flattening (and subsequent negative asphericity) is of a relatively low degree (Lindsay, 2002). It must be remembered that even toric soft lenses will not neutralize the irregular corneal astigmatism that often occurs as a result of RK.

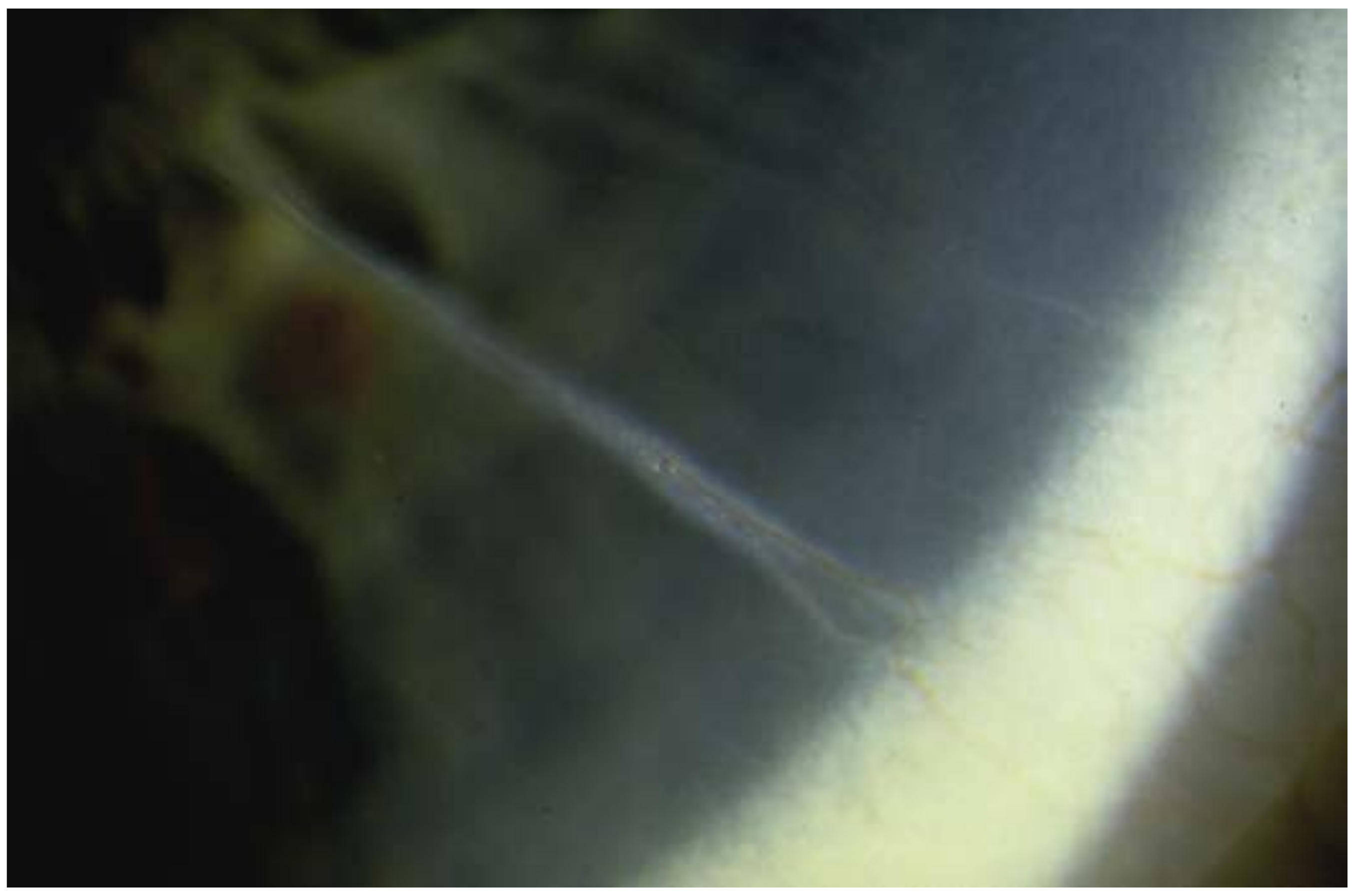


Fig. 30.6 Incisional neovascularization secondary to the wearing of a low-water-content soft contact lens.

Incisional neovascularization is a common complication associated with the use of soft contact lenses following RK (Fig. 30.6). Its incidence can be minimized through the use of high-oxygen-permeability silicone hydrogel lenses used on a daily-wear basis.

RIGID LENSES

Following RK, the cornea may exhibit significant corneal flattening with only minimal mid-peripheral flattening (approximately 0.1–0.2 mm flatter than its preoperative curvature). Therefore, in the fitting of a rigid lens, a back optic zone radius (BOZR) should be selected to align with the 'more normal' mid-peripheral cornea, approximately 4.0 mm from the centre along the horizontal meridian.

The radius of the postoperative mid-peripheral cornea can be determined through corneal mapping. Alternatively, a diagnostic lens can be selected with a BOZR that is 0.1–0.2 mm flatter than the preoperative flat K-reading and the fit can be evaluated. The appropriate BOZR should result in a fluorescein pattern that displays apical clearance over the flatter central cornea and a zone of mid-peripheral bearing at the 3 and 9 o'clock locations (Fig. 30.7). The lens should display unobstructed movement along the vertical meridian.

Lens decentration is a common problem following RK. It is often the result of uneven wound healing, which creates geographic surface elevations on which the lens pivots (Fig. 30.8). Lens decentration is best resolved by increasing the overall lens diameter to 10.5 mm or larger, or by moving to a scleral lens design. Final lens power is best determined by performing a sphero-cylinder refraction over a well-centred diagnostic lens.

SCLERAL LENSES

Parminder and Jacobs (2015) reviewed the use of scleral lenses for refractive surgery complications and noted that a disproportionate fraction of reports in the literature related to patients who had previously undergone radial keratotomy. This is in part

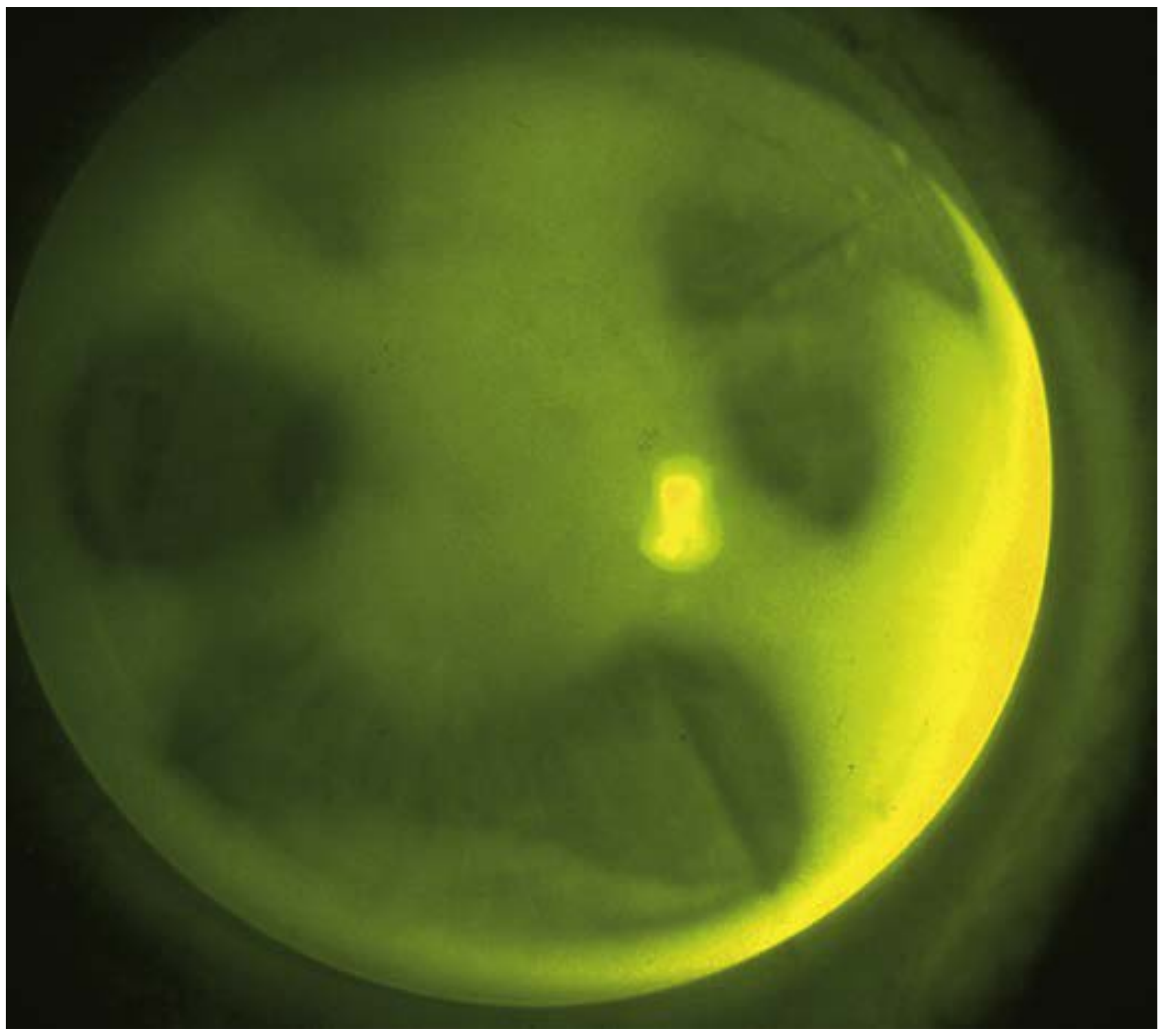


Fig. 30.7 Fluorescein pattern post-radial keratotomy. The cornea has a central flat K of 8.76 mm and a mid-peripheral curvature (4 mm temporal) of 7.94 mm. The lens has a back optic zone radius of 7.94 mm.

due to the greater challenges faced in fitting the post-RK cornea. Fortunately, contemporary approaches to scleral lens fitting with no corneal contact and minimal on-eye movement enable many former RK patients to be rehabilitated.

Contact Lens Fitting Following Intrastromal Corneal Ring Segments

Intrastromal corneal ring segments have been used as a refractive surgery method for the treatment of myopia and keratoconus. The aim is to alter corneal topography to be flatter and more regular, respectively. However, the changes in corneal anatomy created by the intrastromal rings may make contact lens fitting more challenging. Corneal irregularity may be exacerbated owing to drastic variations in corneal elevation over the intrastromal ring and directly adjacent to the ring. This irregularity in elevation leads to difficulty in centring a lens on the eye and problems with bubbles forming under the contact lens over areas of corneal depression (Hladun and Harris, 2004). When successfully fitted, contact lenses over intrastromal corneal rings can improve vision significantly. This may be feasible with soft toric lenses or, if that proves unsuccessful, with a piggyback system (Carballo-Alvarez et al., 2014).

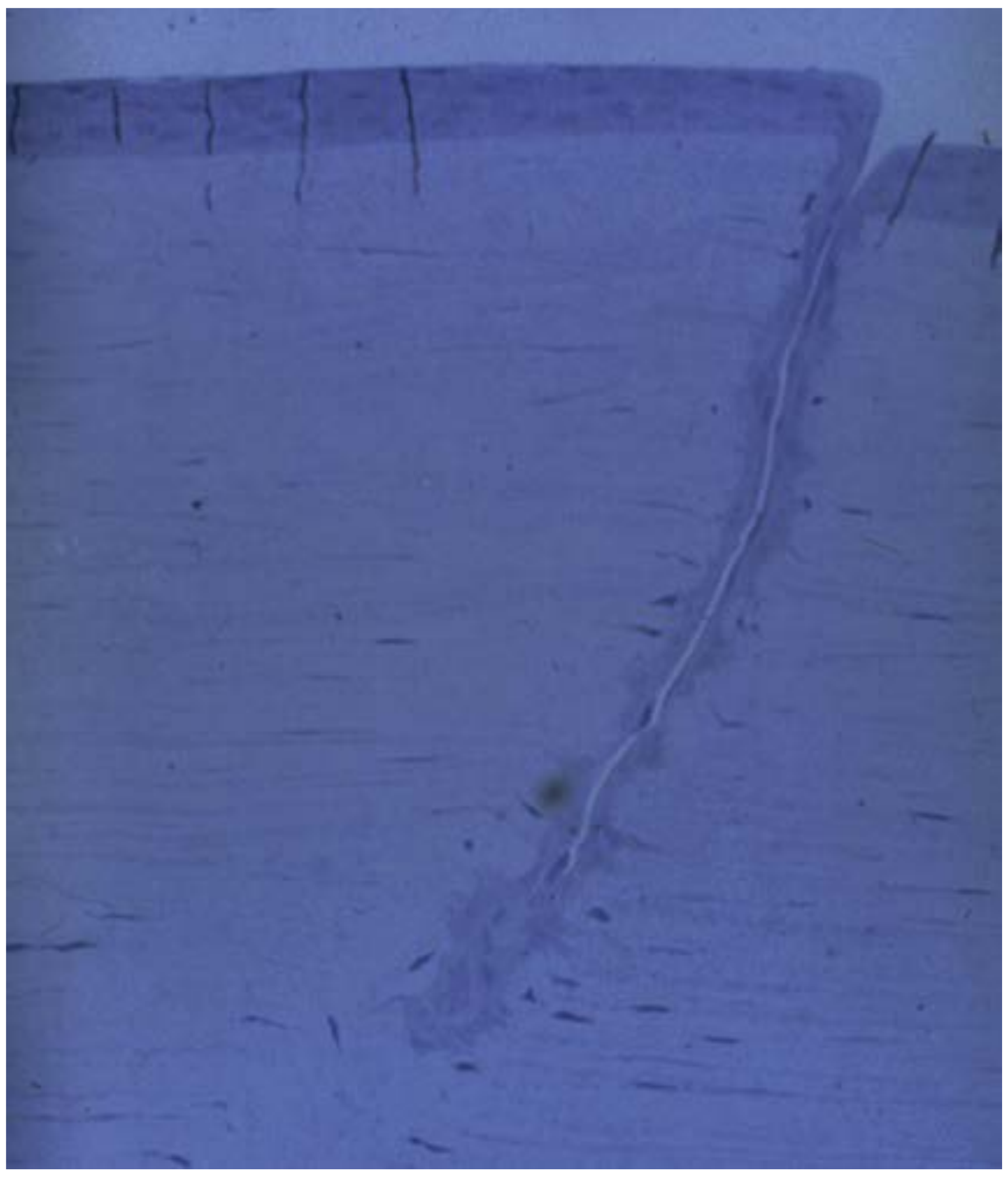


Fig. 30.8 Pivot point created by uneven wound apposition, seen here at the top right corner of the tissue section (cat eye).

Conclusion

Over time, new refractive surgery techniques have emerged and older techniques are abandoned or modified through modern technology. However, the altered topographies left in the wake of less-than-successful procedures remain. Therefore, contact lenses will continue to play an important role in the lives of individuals whose corneas have been permanently compromised by refractive surgery. Whether contact lenses are used in lieu of or in conjunction with further refractive surgery, the outcome can be a positive experience for the patient. With ongoing refinements in lens materials and designs, contact lens technology will continue to meet the challenges posed by future refractive surgery procedures.

ACKNOWLEDGEMENTS

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Access the complete references list online at http://www.expertconsult.com.

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31

Post-keratoplasty

BARRY A WEISSMAN

Introduction

Corneal transplantation (keratoplasty or KP) is a surgical procedure by which diseased corneal tissue is removed and replaced by donor material (a corneal graft) (Fig. 31.1).

Corneal transplantation resulting in relatively clear grafts was first reported in the ophthalmic literature with Reisinger's rabbit experiments (1824). Such homografts (or allografts) are transplants within the same species (i.e. from one rabbit to another or from one human to another) and are the most common form of KP. Von Hippel (1888) made several unsuccessful attempts to graft a glass prosthesis, but his work forms the basis of modern KP. Von Hippel and others also used animal corneas as donors for humans: these are heterografts – transplants from one species to another – and are commonly rejected. Zirm (1906) is credited with the first human corneal transplant (treating a leukoma due to a quicklime burn) to retain a moderate degree of transparency. The introduction of McCarey–Kaufman (MK) medium (McCarey and Kaufman, 1974; McCarey et al., 1976) enabled donor human cornea to be stored for 3–4 days. Further advances based on tissue culture techniques extended the preservation of donor tissue for up to 30–40 days (Doughman et al., 1976; Sperling, 1979, Doughman, 1980; Sperling et al., 1981). Autografts, wherein one eye provides the donor cornea for the other, although rare for obvious reasons (the author has seen two human corneal autografts in his career; Fig. 31.2), have limited, if any, risk of rejection. Artificial corneal grafts, such as the Dohlman 'Kpro™', are an area of active research and development (Dohlman et al., 2002, Griffith and Harkin, 2014) and have had some recent success (Srikumaran et al., 2014) (Fig. 31.3).

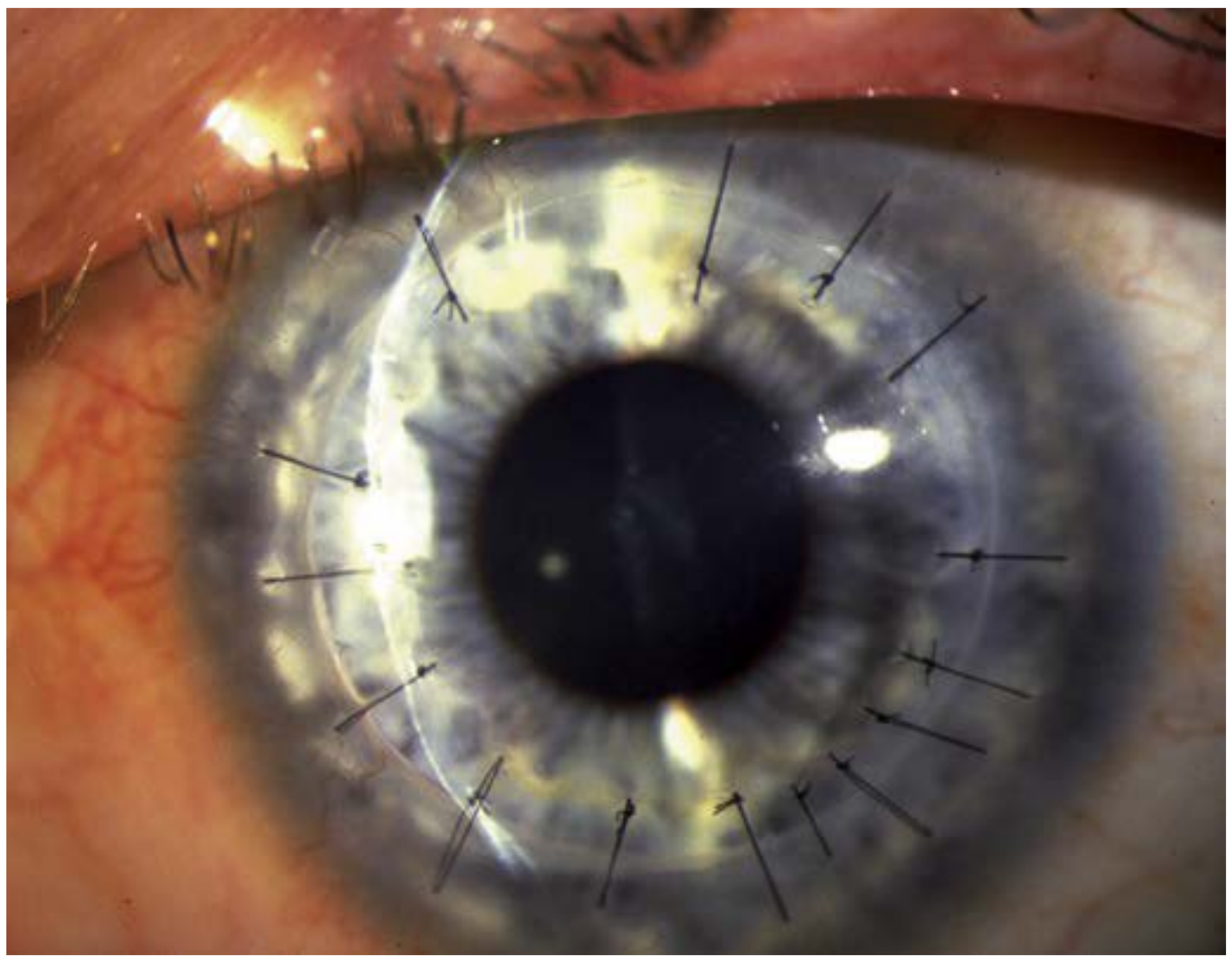

Fig. 31.1 A penetrating keratoplasty with interrupted sutures.

Corneal grafts are performed for the following reasons:

- optical – to restore visual function by removing scarred or irregular tissues (e.g. in keratoconus, post trauma and infection, corneal dystrophy)
- therapeutic – to treat disease (e.g. to treat an infection by debulking)
- tectonic – to restore, or preclude the loss of, globe integrity
- cosmetic – to improve appearance (e.g. eliminate an unsightly scar in a non-seeing eye).

The indications outlined above are not necessarily mutually exclusive.

Approximately 60 000 to 70 000 KP procedures were performed annually in the USA over the past two decades (Eye Bank Association of America, 2013) with another 2000+ per year over the last decade in the UK (Keenan et al., 2012) and another 1000 in Australia (Coster et al., 2014). With the introduction of enhanced lamellar keratoplasty (LK) techniques, this number appears to be increasing in all three areas.

Indications

The diagnostic indications for corneal grafts include:

- corneal oedema that is severe enough to affect visual function, and painful bullous keratopathy, usually a consequence of Fuchs' endothelial dystrophy or aphakic/pseudophakic endothelial failure
- keratoconus and other forms of corneal ectasia such as pellucid marginal degeneration and Terrien's degeneration. The criteria for performing KP may be when the condition

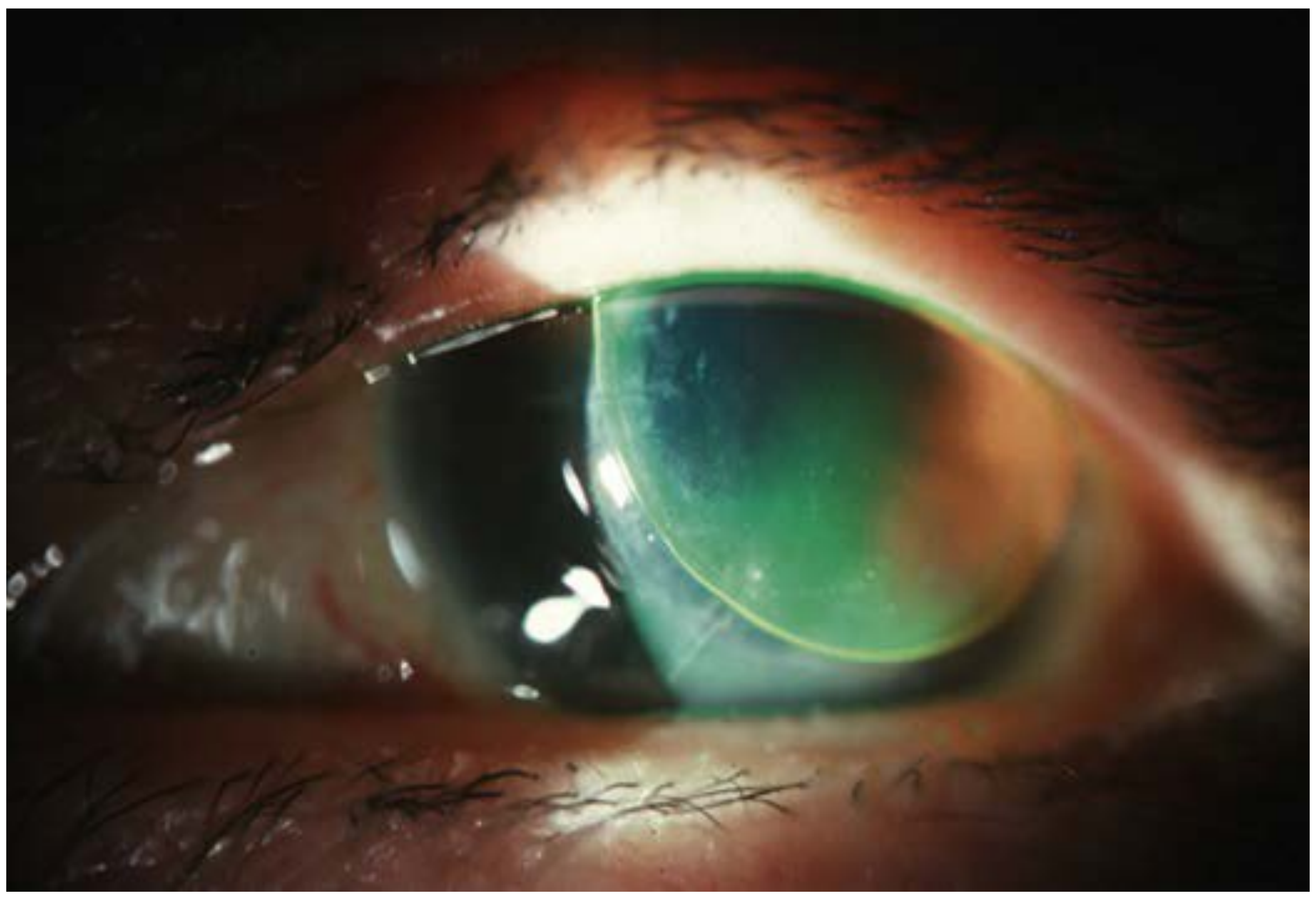

Fig. 31.2 Corneal autograft. This patient had congenital syphilis and when the cornea of her good eye failed, it was grafted with a donor button taken from her contralateral, severely amblyopic eye (to enhance her chances of avoiding rejection) and that donor replaced with a traditional allograft.

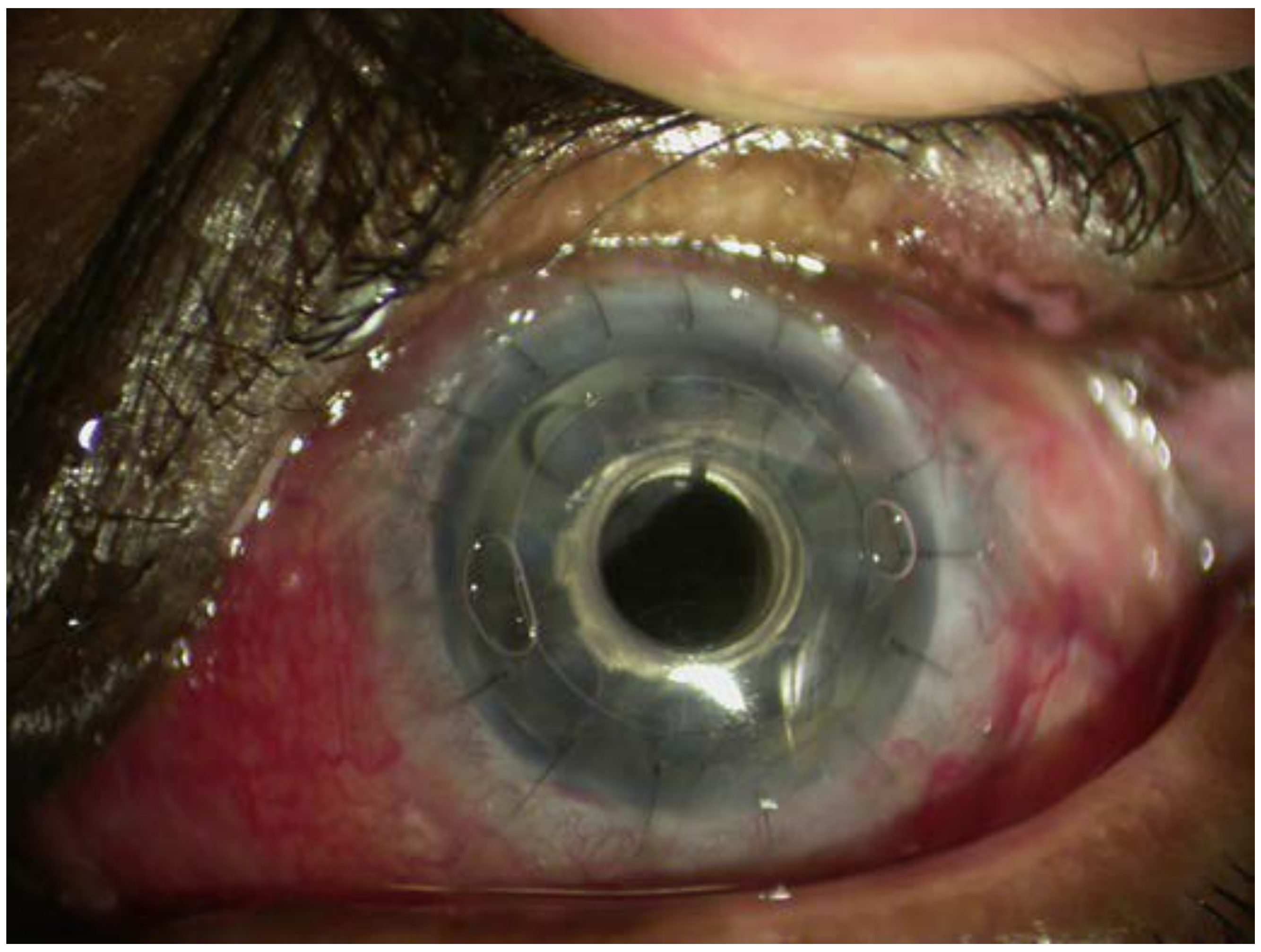

Fig. 31.3 Dohlman keratoprosthesis; note the bandage soft lens in place (by the bubbles seen in the 3/9 zones).

is severe enough to limit vision with contact lens correction to 6/12 or worse, or when contact lens wear can no longer be tolerated for physical or physiological reasons. Approximately 20% of keratoconic patients will eventually come to benefit from corneal transplantation (Lass et al., 1990)

- corneal scars and interstitial keratitis, secondary to trauma and/or infection (e.g. herpetic keratitis)
- visually debilitating forms of corneal dystrophy, such as the transforming growth factor beta 1 (TGFβ1) dystrophies (e.g. granular I or II, lattice, or Reis–Bücklers) and macular corneal dystrophy
- congenital opacities, such as Peters' anomaly or buphthalmos secondary to congenital glaucoma
- previous graft rejection or failure.

Types of Corneal Graft

Full-thickness penetrating keratoplasty (PKP), first using mechanically paired blades to produce square grafts but evolving to circular grafts produced with trephines, has been the standard of care in corneal transplantation for more than 50 years. Patch grafts have long been used to seal corneal leaks, but visual results are not vital. Lamellar procedures (LK), in which only isolated 'sick' layers of the cornea are replaced, however, have evolved rapidly over the past decade.

Development of the IntraLase femtosecond laser allows corneal surgeons to create complex, shaped PKP incisions (e.g. 'top hat', 'mushroom', 'zigzag') that are identical in both host and graft tissue. Called IntraLase-enabled keratoplasty or IEK (or femtosecond-assisted corneal transplant, 'FACT'), this procedure creates PKPs with customized 'interlocking'-edge designs that it is hoped will minimize induced astigmatism and enhance wound strength. Fewer sutures may be required, healing should be faster, and decreased regular and irregular astigmatism will hopefully enhance vision and reduce the need for contact lens correction. The risk for displacement of the graft may also be reduced. A study of 116 keratoconus patients found that the 56 patients treated with IEK had significantly better vision improvement than did those receiving traditional trephine PKP: 3 months postoperatively, significantly more IEK patients were reported to have better best spectacle-corrected visual acuity (BSCVA) ($p = 0.001$) and visual recovery 20/40 or better ($p < 0.001$) and lower topographic astigmatism ($p = 0.001$) (Gaster et al., 2012). An earlier large study had reported a lower (30%) improvement in 2800 patients treated with traditional trephine PKP (Vail et al., 1997).

Epikeratoplasty – a short-lived surgical procedure was this early LK variant wherein a precut (to a specific optical power) donor cornea was applied to the anterior surface of the intact host stroma (the epithelium but not the stroma was removed) in an effort to address aphakia, keratoconus or high myopia. It was found to result in poor vision (secondary to interface problems) and has been abandoned.

Superficial corneal diseases have long been alternatively treated with anterior lamellar keratoplasty (ALK) wherein, following initial partial-thickness trephination, a blunt blade was used mechanically to separate a deep plane in the tissue to allow replacement of only the diseased superficial cornea. ALK retains the host endothelium to thereby reduce both immunological rejection and physiological failure. ALK optical results were poor, however, and were usually reserved for either the corneal periphery or as tectonic procedures later followed by PKP to allow optical rehabilitation. Deep anterior lamellar keratoplasty (DALK) is a newer LK that utilizes air, water or a microkeratome to separate the deep stromal fibres from Descemet's membrane (Archila, 1985; Price, 1989; Sugita and Kondo, 1997; Busin et al., 2005). It is thought that deepening the position of the interface between the replacement and host cornea improves the potential visual results; DALK has gained some popularity owing to its theoretical advantages, in treatment of keratoconus in particular, although its practical superiority to PKP remains in question (Coster et al., 2014; Keane et al., 2014).

Several endothelial lamellar keratoplasty (ELK) procedures to replace only damaged posterior corneal tissues (as in Fuchs' dystrophy) have evolved – from deep lamellar endothelial keratoplasty (DLEK) (Terry and Ousley, 2003; Watson et al., 2004) to Descemet's stripping endothelial keratoplasty (DSEK) (Melles, 1998; Price and Price, 2006), or an automated version using a microkeratome called Descemet's stripping automated endothelial keratoplasty (DSAEK) (Gorovoy, 2006), and further to Descemet's membrane endothelial keratoplasty (DMEK) (Price and Price, 2013), wherein only the endothelial layer is replaced (Fig. 31.4), leaving the host anterior corneal surface hopefully smooth and intact so that these patients may not require contact lens correction. Price and Price (2013) further state that DMEK in particular mitigates the two principal liabilities of KP: immunological graft reactions (Anshu et al., 2012) and secondary glaucoma from prolonged topical corticosteroid use.

DLEK, DSEK, DSAEK, and DMEK, each more technically demanding than its predecessor, theoretically also offer rapid healing, more acceptable refractive outcomes and better retention of corneal strength, compared with PKP – but surgery is technically very demanding and donor adherence may be challenging.

With increasing optical success of DSEK, DMEK, and DALK, PKP has lost its position as the sole dominant KP technique over the past decade, but at the time of writing the discussion about which procedure may prove optimal for many patients continues (Coster et al., 2014).

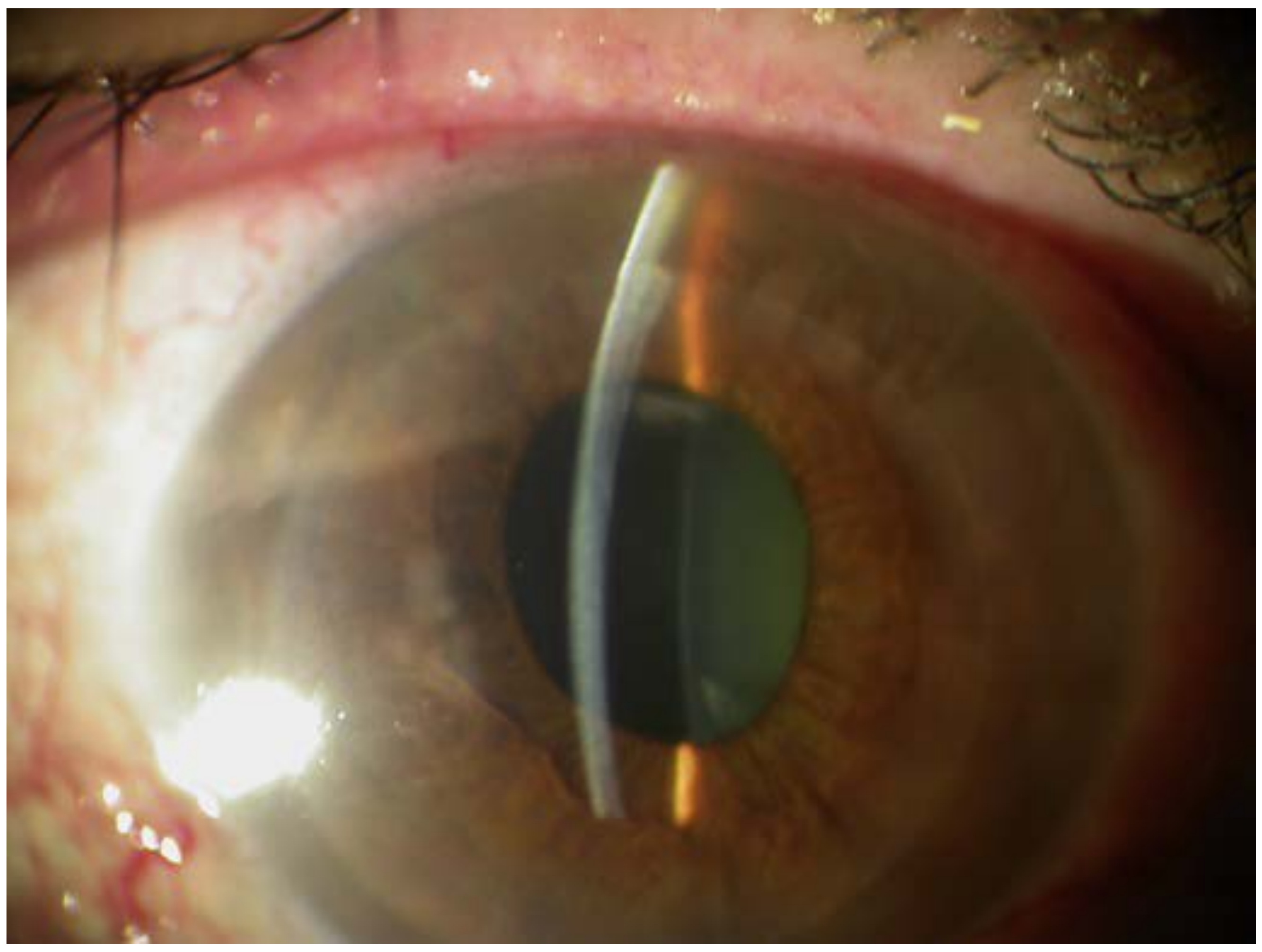

Fig. 31.4 A cornea post-Descemet's stripping endothelial keratoplasty (for treatment of the combination of iris naevus or Cogan–Reese syndrome; Chandler's syndrome; and essential iris atrophy, called ICE syndrome). Note increased corneal thickness extending into the anterior chamber seen in the optical section superiorly.

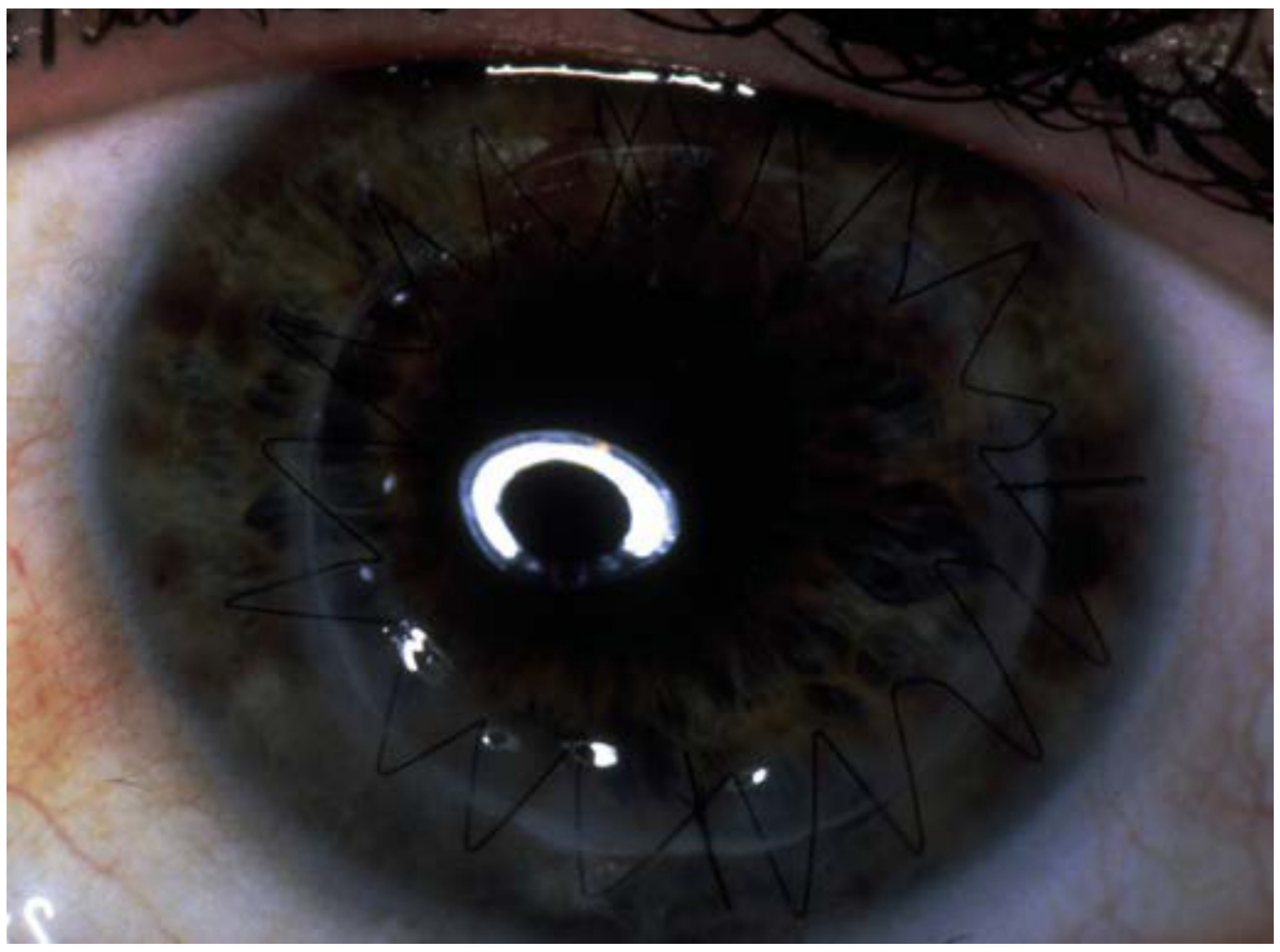

Fig. 31.5 Irregular surface astigmatism in a graft, as indicated by the distorted reflex of a perfectly circular flash gun. (Courtesy of Desmond Fonn, Bausch & Lomb Slide Library.)

BOX 31.1 LEXICON OF VARIOUS KERATOPLASTY PROCEDURES

ALK	anterior lamellar keratoplasty
DALK	deep anterior lamellar keratoplasty
DLEK	deep lamellar endothelial keratoplasty
DMEK	Descemet membrane endothelial keratoplasty
DSAEK	Descemet stripping automated endothelial keratoplasty
EK	endothelial keratoplasty
KPro	corneal prosthesis
LK	lamellar keratoplasty
PKP, PK	penetrating keratoplasty
PLK	posterior lamellar keratoplasty
SALK	superficial anterior lamellar keratoplasty

No modern discussion of KP, however, would be complete without a discussion of artificial corneas. Though viable artificial cornea materials and surgical procedures have long been sought so as to address insufficient human transplant material, immunology and religious concerns, only recently has this become a practical reality (Dohlman et al., 2002, Srikumaran, 2014); several competitive designs may shortly be available (Griffith and Harkin, 2014). Box 31.1 presents the lexicon of various keratoplasty procedures.

Irregular Corneal Topography Following KP

The main optical challenge following traditional PKP (perhaps lessened but not eliminated with the advent of FACT and other forms of ALK) has been irregular surface astigmatism (Fig. 31.5). Optical rehabilitation of these distorted corneas remains a principal function of specialty contact lens practice, and PKP remains, despite the growth in the LKs, a common patient presentation. Hence we will discuss care of this disease in depth. It should also be noted that according to van Dijk et al. (2013): 'after successful DMEK, 23 of 262 eyes (9%) showed subnormal spectacle [corrected vision] and/or monocular diplopia due to corneal scarring, surface irregularities, or undetectable optical imperfections that could be managed by contact lens fitting. Prolonged preoperative corneal edema for more than 12 months may be a risk factor for diffuse irregular astigmatism after DMEK ... '.

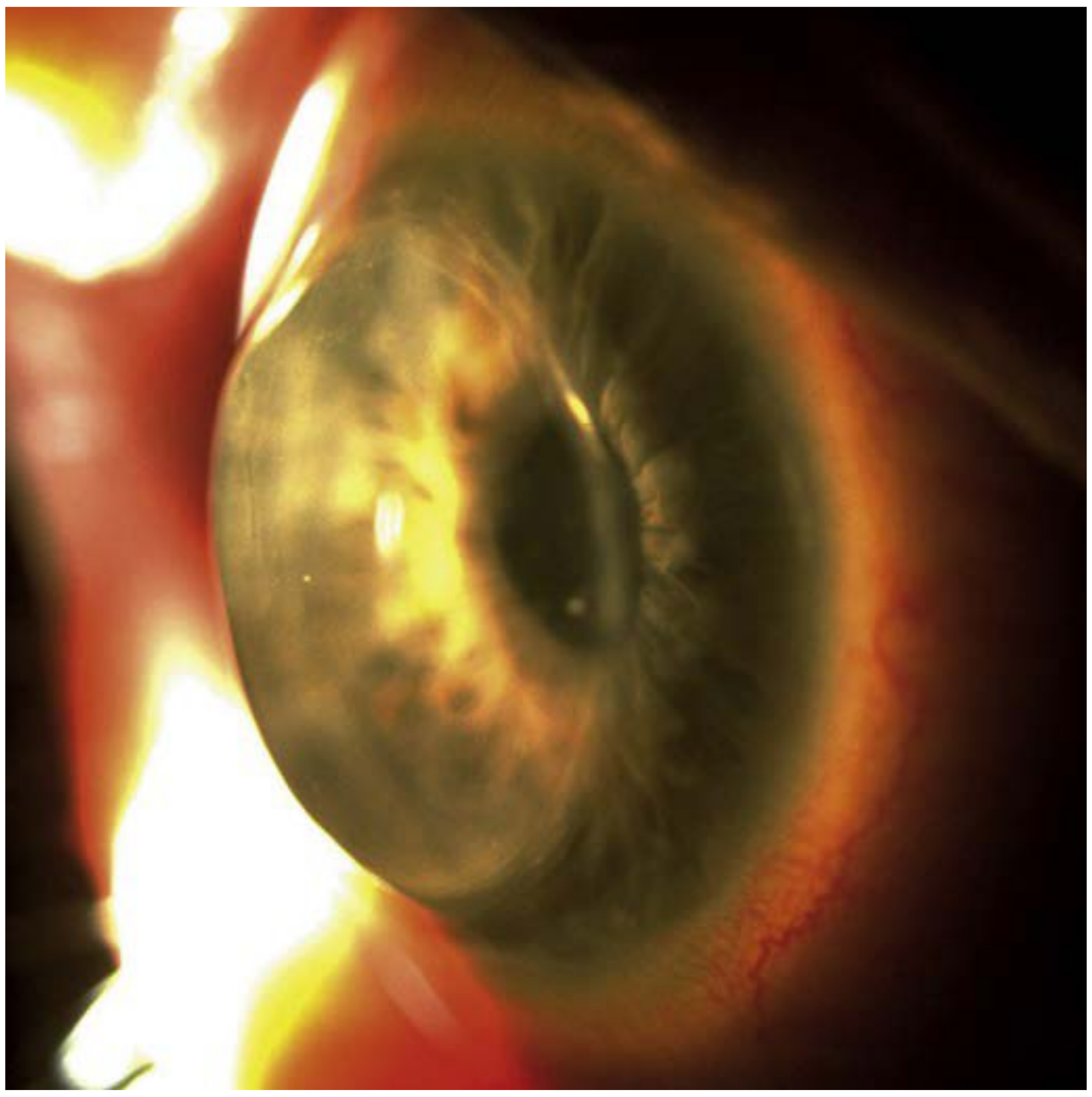

Fig. 31.6 Proud graft totally elevated above the host corneal surface in a keratoconic eye. (Courtesy of Robert Terry, Bausch & Lomb Slide Library.)

Waring et al. (1992) documented the prevalence of the various forms of corneal topography following trephine PKP as: 'prolate' (30%), 'oblate' (30%), 'mixed' (20%), 'asymmetric' (10%) and 'steep to flat' (10%). Phillips (1997) discussed these corneal topographic outcomes in more clinically descriptive terminology as: 'nipple' or steep; 'proud', whereby the graft is totally or partially elevated above the host corneal surface (Fig. 31.6); 'sunken', whereby the graft is depressed below the

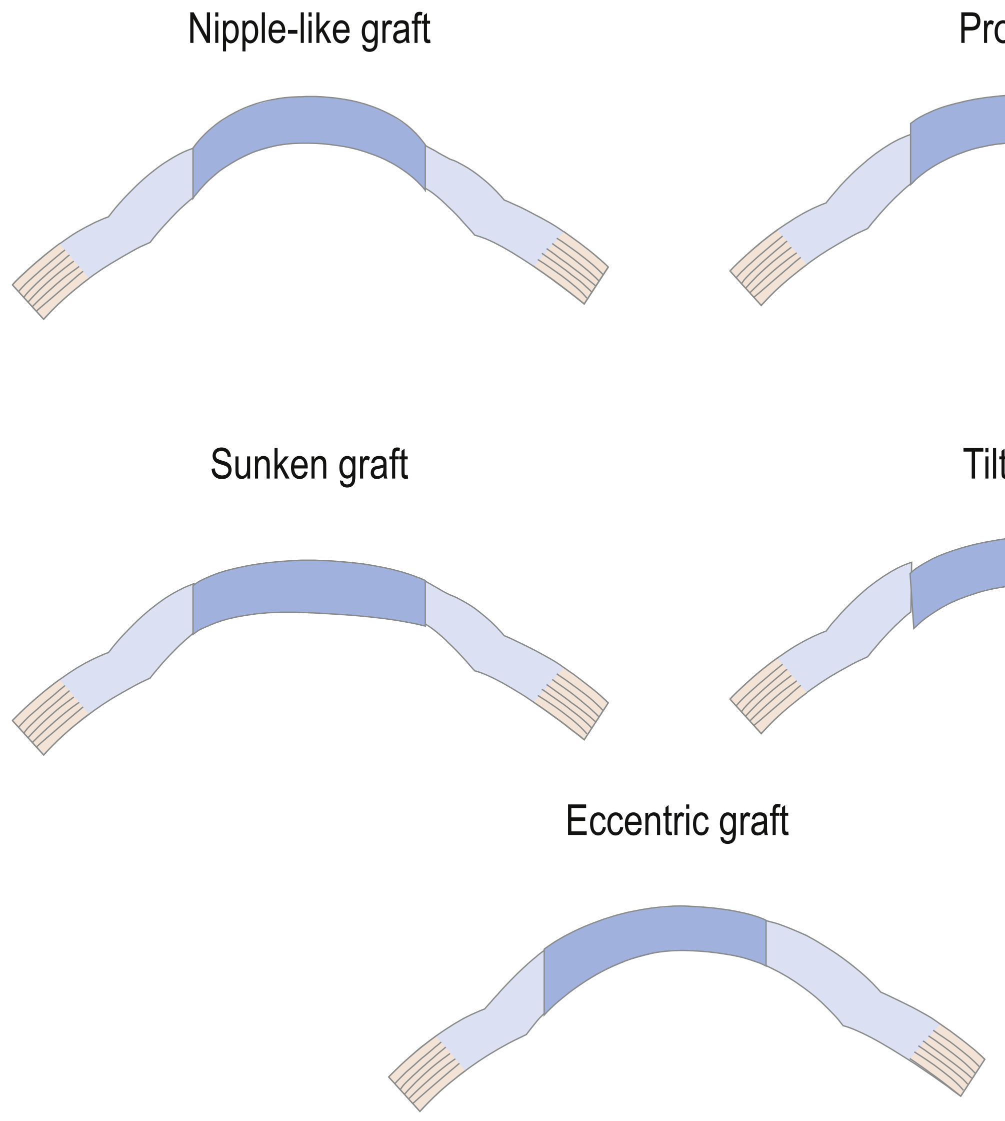

Fig. 31.7 Graft profiles. (Adapted from Phillips, A. J. (1997) Postkeratoplasty contact lens fitting. In M. J. Harris (ed.) Contact Lenses for Pre- and Post-Surgery (pp. 97–132). St Louis: Mosby.)

host surface; and 'tilted' or 'eccentric'. These outcomes are illustrated in Fig. 31.7.

Hoppenreijs et al. (1993) suggested that causes of these topographic outcomes include:

- suboptimal cutting of the donor, the host, or both
- eccentric placement of the graft
- elevation of the graft edge during healing, with poor wound approximation
- loosening of sutures
- localized abnormal healing
- initial corneal irregularity (e.g. keratoconus).

A second common optical problem following corneal grafts is anisometropia.

Suture Techniques for PKP

Contact lens clinicians should have a general appreciation of suture techniques used for KP because patients commonly present for fitting or aftercare visits with some or all sutures still in place. Sutures may be of the following forms:

- running (or continuous) – a continuous suture forms a zigzag pattern across the host–graft interface, which extends around the full circumference of the graft (Fig. 31.8)
- double running – two continuous sutures form a zigzag pattern across the host–graft interface, which extends twice around the full circumference of the graft
- interrupted – a number of single sutures, commonly 12 or 16, which are equally spaced around the graft circumference (see Fig. 31.1)
- combination – both running and interrupted sutures are used.

These various forms of suturing are illustrated in Fig. 31.9.

Most surgeons use either double running or one running and several interrupted sutures as the technique of choice. Square grafts (common many years ago) are rarely if ever currently performed, but may be occasionally seen and followed. In a prospective study, astigmatism was found to be the least following double running sutures compared with interrupted or single running sutures 18 months after PKP (Kim et al., 2008). At some point – commonly some 3–6 months after surgery – either one running suture, or the interrupted sutures, is/are removed, often selectively in an effort to moderate astigmatism. One running suture, or several interrupted sutures, is/are commonly left in place indefinitely, only to be removed if problems or breaks develop. Interrupted sutures alone are favoured when PKP must be attempted in the face of active anterior-segment inflammation or corneal neovascularization to permit later individual removal when appropriate. Adjunctive surgery, relaxing incisions, additional sutures, or even wedge resection procedures have been used with variable success to address postoperative astigmatism (Budak et al., 1998).

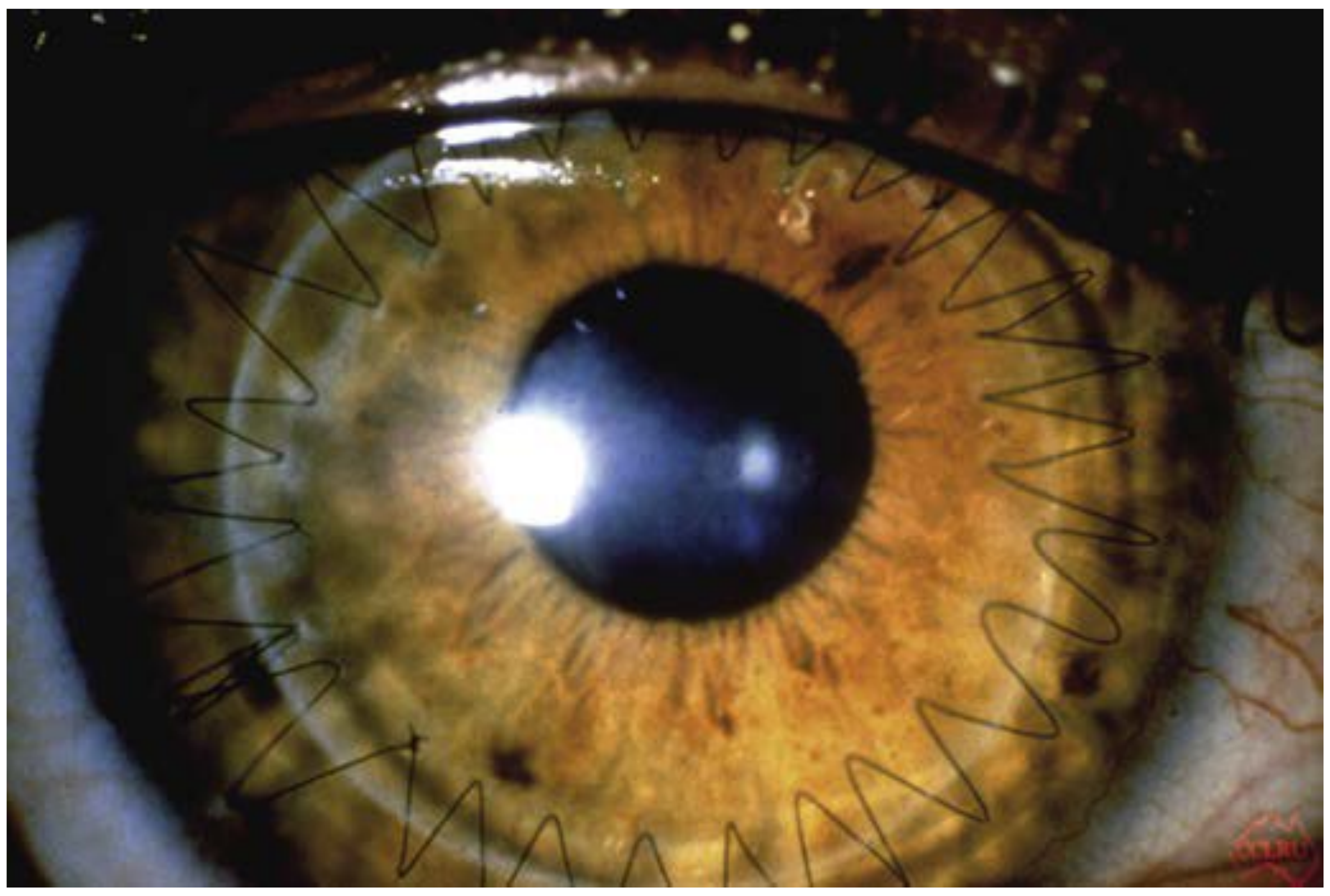

Fig. 31.8 A penetrating keratoplasty with a single running suture. (Courtesy of Robert Terry, Bausch & Lomb Slide Library.)

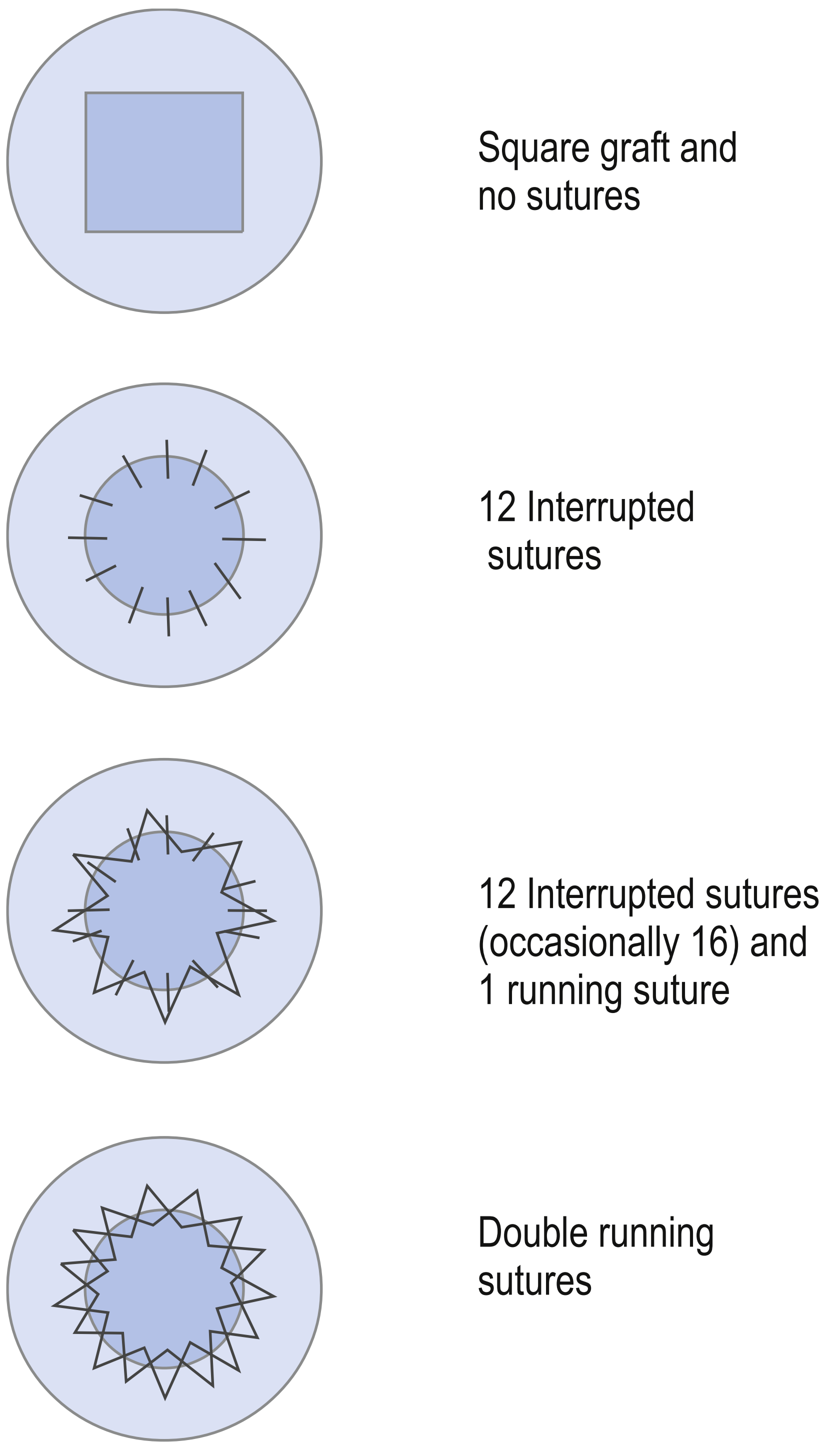

Fig. 31.9 Grafts and sutures.

Indications and Contraindications for Contact Lens Wear Post-corneal Grafts

The indications for contact lens use following corneal grafts are primarily postoperative irregular or high astigmatism, and secondarily anisometropia (e.g. as will occur in aphakia). Between 20% and 60% of trephine-cut post-PKP patients benefit optically from contact lens wear (Ruben and Colbrook, 1979; Lass et al., 1990; Smiddy et al., 1992; Silbiger et al., 1996; Wietharn and Driebe, 2004). Bandage hydrogel contact lenses are also sometimes used as drug delivery devices or to treat non-healing epithelial defects in the immediate postoperative period and for wound dehiscence at any time (Mannis and Zadnik, 1988) (Fig. 31.10). Bandage soft lenses are also used both for protection (e.g. dehydration) and for optical 'smoothing' over the Dohlman KPro artificial cornea (Dohlman et al., 2002).

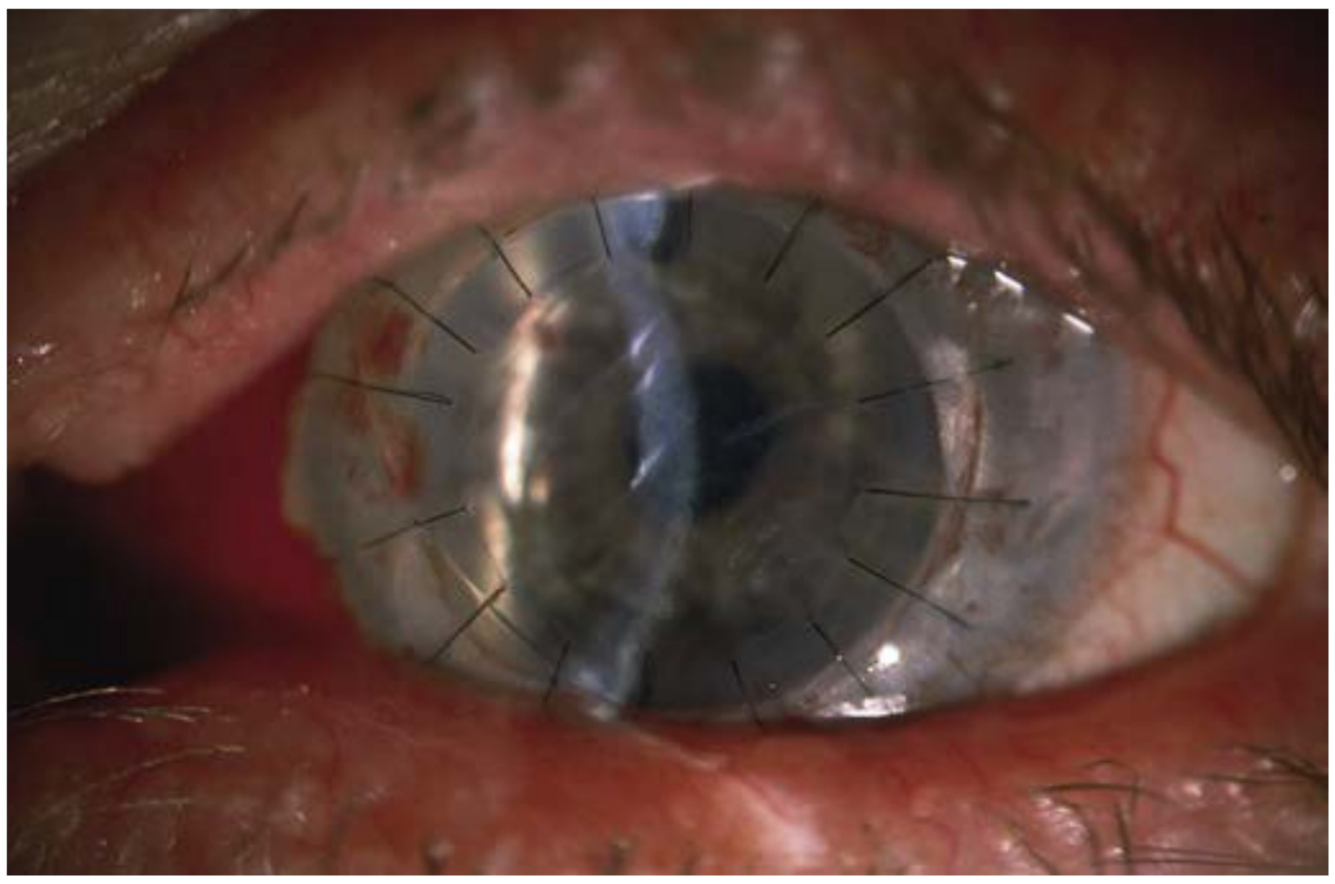
Fig. 31.10 A bandage hydrogel lens used 1 day after surgery to cover a graft that has been secured with interrupted sutures.

Contact lens contraindications are as follows:

- a good (or even just adequate) visual result with spectacle correction alone
- anticipated poor compliance with contact lens care.

The clinician should also be concerned about several other relative contraindications (most of which increase both risks of infection and those of rejection), including:

- decreased corneal sensitivity – expected during the first year postoperatively (Ruben and Colbrook, 1979; Darwish et al., 2007)
- dry eyes – tear break-up time was found to be significantly shorter 3 and 12 months after keratoplasty (Darwish et al., 2007)
- blepharitis
- dacryocystitis.

Patients with collateral systemic diseases, such as acne rosacea and rheumatoid arthritis, which can both lead to dry eyes and increased risk of corneal ulcer / melts and neovascularization, need to be monitored carefully. Patients with diabetes or other immune system depressions, which can increase the risk of corneal infection, should also be approached with extra caution, and monitored frequently.

General Concerns

Careful consideration needs to be given to the time period that should be allowed to elapse following surgery before contact lenses are fitted, if so indicated. Previous authors suggested 'a year post-surgery, when all sutures have been removed' (Soper et al., 1964); however, this advice is not appropriate today because some sutures are now not removed unless they break or otherwise become problematic. The current approach, therefore, is that contact lenses can be fitted whenever the graft is considered to have healed sufficiently to tolerate lens wear (Wilson et al., 1992). Contact lens application therefore may begin as early as 3–6 months postsurgery, and often with one or more sutures remaining. When sutures do come out during the postoperative course, after patients are already using contact lenses, the clinician should re-evaluate the patient before lens wear is resumed. A new fitting is occasionally indicated to address changes in corneal topography, optics, or both (more so with the removal of running sutures than with individual interrupted sutures, although surprises can occur) (Mathers et al., 1991; Mader et al., 1993; Langenbucher et al., 2005).

Topical steroid treatment is known to potentiate secondary glaucoma, cataract and corneal infection, but many post-corneal-graft patients will continue to use topical steroids consistently or intermittently for the rest of their lives to suppress rejection. Hence, the clinician and patient must tolerate such risks and the patient should be reasonably monitored by both the corneal surgeon and the contact lens practitioner.

It is now accepted that extended wear of contact lenses may enhance the prevalence and severity of all the physiological complications of lens wear. These may be even more serious in the post-KP patient than in the cosmetic contact lens patient, as many such complications potentiate graft rejection. The clinician must consider whether to advise extended or daily wear for each patient, accepting that some patients will be elderly or in other ways infirm and therefore unable to care for contact lenses. Under certain conditions, therefore, extended wear and its attendant risks may also need to be accepted by both clinician and patient.

Lens-fitting Techniques

Rigid lenses remain the overwhelming device of choice for the majority of post-KP patients because they efficiently and effectively optically mask most regular and irregular astigmatism. Soper et al. (1964) suggested that rigid lenses (then referring to non-oxygen-permeable polymethyl methacrylate) should be fitted so as to ride within the PKP, meaning that the overall diameter (OAD) of the lens would probably be less than 7.5–8.0 mm. The subsequent introduction of rigid gas-permeable materials encouraged the use of lenses with larger OADs (9.0 mm to as much as 11.0 mm) that override the entire graft without causing hypoxic difficulties (Woodward, 1997). As rigid contact lenses tend to 'ride' towards and over the highest corneal point, larger-OAD lenses allow enhanced stability and centration – which is still often difficult to achieve, especially on sunken or tilted PKPs. Excessively flat cornea topographies post-PKP, often associated with donor / hosts of equal diameter, may be especially difficult to fit with rigid lenses (Lagnado et al., 2004). Ozbek and Cohen (2006) reported good results with the use of very-large-OAD (11.2 mm) rigid lenses on a series of 27 irregular corneas (primary indication flat central and steep inferior corneal topography), including 6 post-PKP.

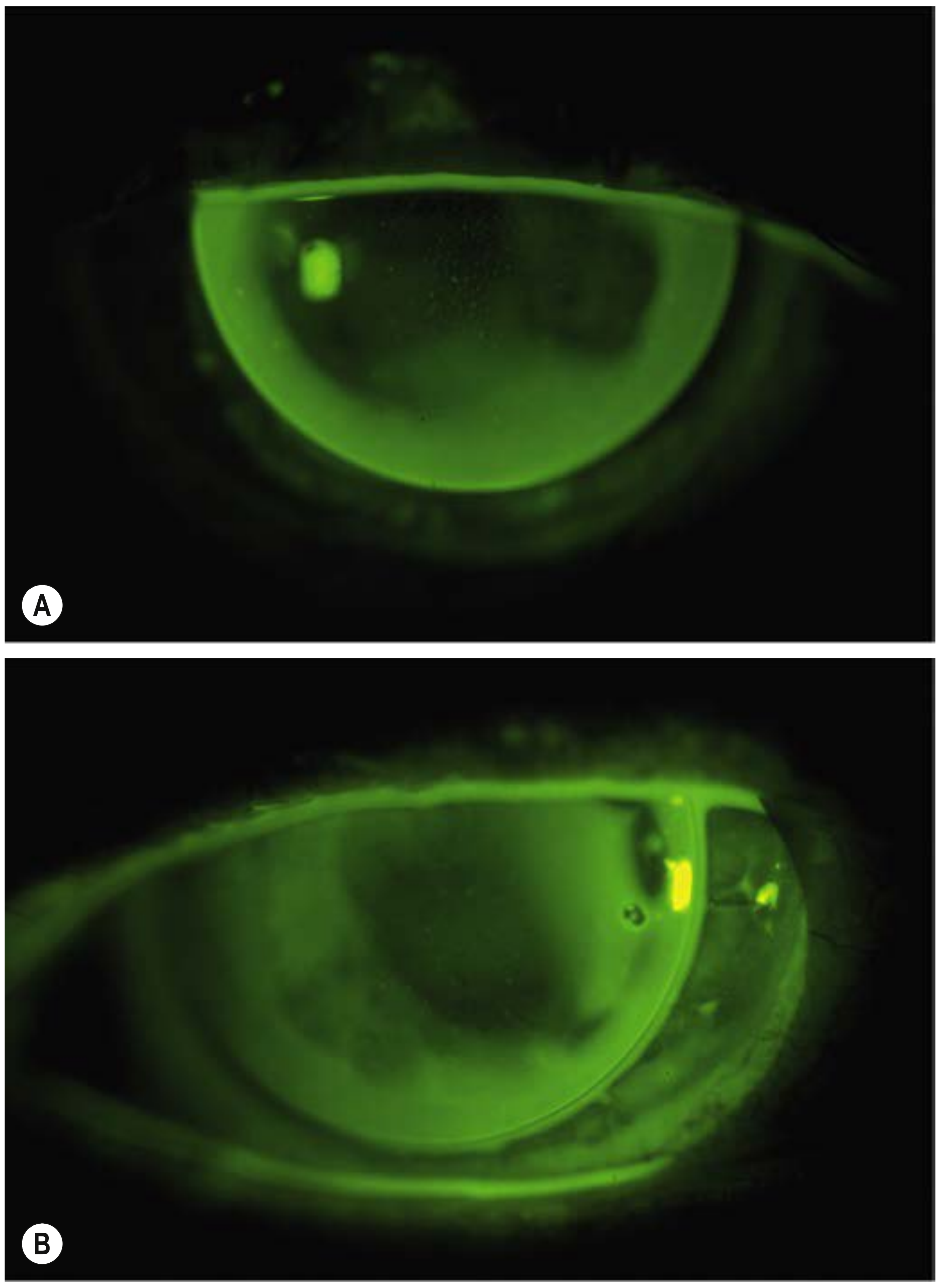

Fig. 31.11 Examples of fluorescein patterns observed on fitting rigid lenses to corneas with imperfect grafts. (A) Plateau fit on proud graft. (B) Tilted sunken graft with small nipple; note that the contact lens partially rests on graft–host interface with running suture.

They selected the initial base curve equal to the topographically determined central flat value and then modified their lenses as appropriate with the clinical goal of minimal lens decentration.

The back optic zone radius of a rigid lens should be selected, with initial assistance of keratometry or corneal topography measurements, so as to achieve some form of irregular corneal surface alignment, with neither excessive touch nor pooling of tears. Examples of fluorescein patterns obtained with rigid lenses fitted to imperfect corneal grafts are shown in Fig. 31.11.

Toric and bitoric rigid designs are occasionally helpful in fitting PKP corneas exhibiting relatively regular astigmatism, and occasionally tilted and eccentric grafts. Weissman and Chun (1987) found that 7 of a series of 23 eyes fitted with bitoric design rigid lenses for irregular astigmatism were post-PKP and the majority of these (6 of 7 or 85%) were felt to be clinically 'successful.' Phan et al. (2014) similarly found that bitoric RGP corneal lenses were effective at managing higher values of irregular corneal astigmatism.

Consideration needs to be given to edge design in fitting rigid lenses to graft corneas. Some corneal surfaces can be fitted with standard edge parameters. Many abnormal corneal shapes require flatter than standard, or steeper than standard, or even reverse-geometry edge designs (Lin et al., 2003) to achieve mechanically acceptable corneal surface alignment, tear exchange and appropriate lens positioning.

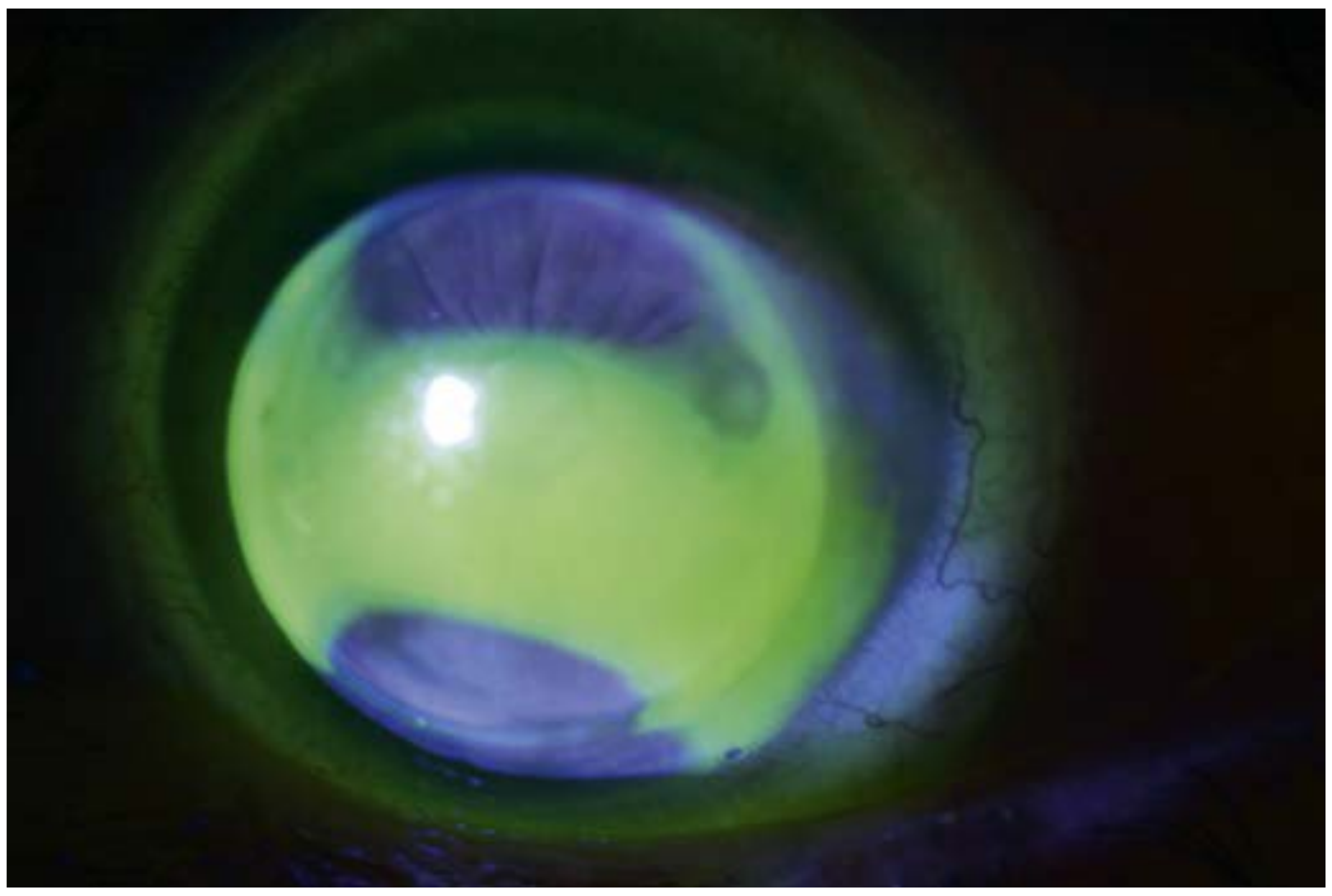

Fig. 31.12 A hybrid lens (in this case a SynergEyes™) is shown on a penetrating keratoplasty eye. Note arcuate areas of touch at the graft–host interface at both 12 and 6 o'clock as well as central corneal clearance of the tear film, or 'pooling', shown with high-molecular-weight Fluoresoft, desirable in this kind of hybrid contact lens.

Both Genvert et al. (1985) and Mannis et al. (1986) suggest that the overall success rate of rigid contact lens wear post-PKP approaches 80%.

Hydrogel contact lenses, both standard and in custom parameters, may be occasionally helpful, especially for the following situations:

- high refractive errors with lesser degrees of astigmatism
- rigid lens intolerance
- acceptance of a less than optimal visual result
- protection of KPro [the keratoprosthesis produced by Claes Dohlman (Dohlman et al., 2002)].

(Hydrogel lenses here include both non-silicone and silicone hydrogels, the latter offering enhanced corneal oxygen supply, which theoretically should be advantageous to a cornea following a corneal graft from a physiological perspective.)

Hybrid lens designs can be beneficial in post-PKP fitting; these include the following:

- 'piggyback' – where a top rigid lens is fitted upon a bottom hydrogel lens (Baldone, 1973); silicone hydrogels are often employed now as the bottom hydrogel lens to enhance oxygen supply (Weissman and Ye, 2006) and thereby decrease the stimulus to neovascularization
- SynergEyes™ (replacing both Saturn II and Sofperm) – a lens with a rigid centre and hydrophilic periphery ('skirt') (Fig. 31.12)
- scleral GP rigid lenses (Daniel, 1976; Schein et al., 1990; Pecego et al., 2012; see Chapter 21). (Fig. 31.13).

The above hybrid designs often allow optimal vision, similar to rigid lenses, but such lenses are expensive, complex in mechanical fitting, often lead to occlusive lens problems, and may induce hypoxia or binding, which in turn can increase the prevalence and severity of many complications, particularly neovascularization (Fig. 31.14). Scleral GP lenses are fitted by the same technique as for non-graft eyes (see Fig. 31.13); the clinician should use a material of high oxygen permeability and must initially achieve some corneal clearance, both

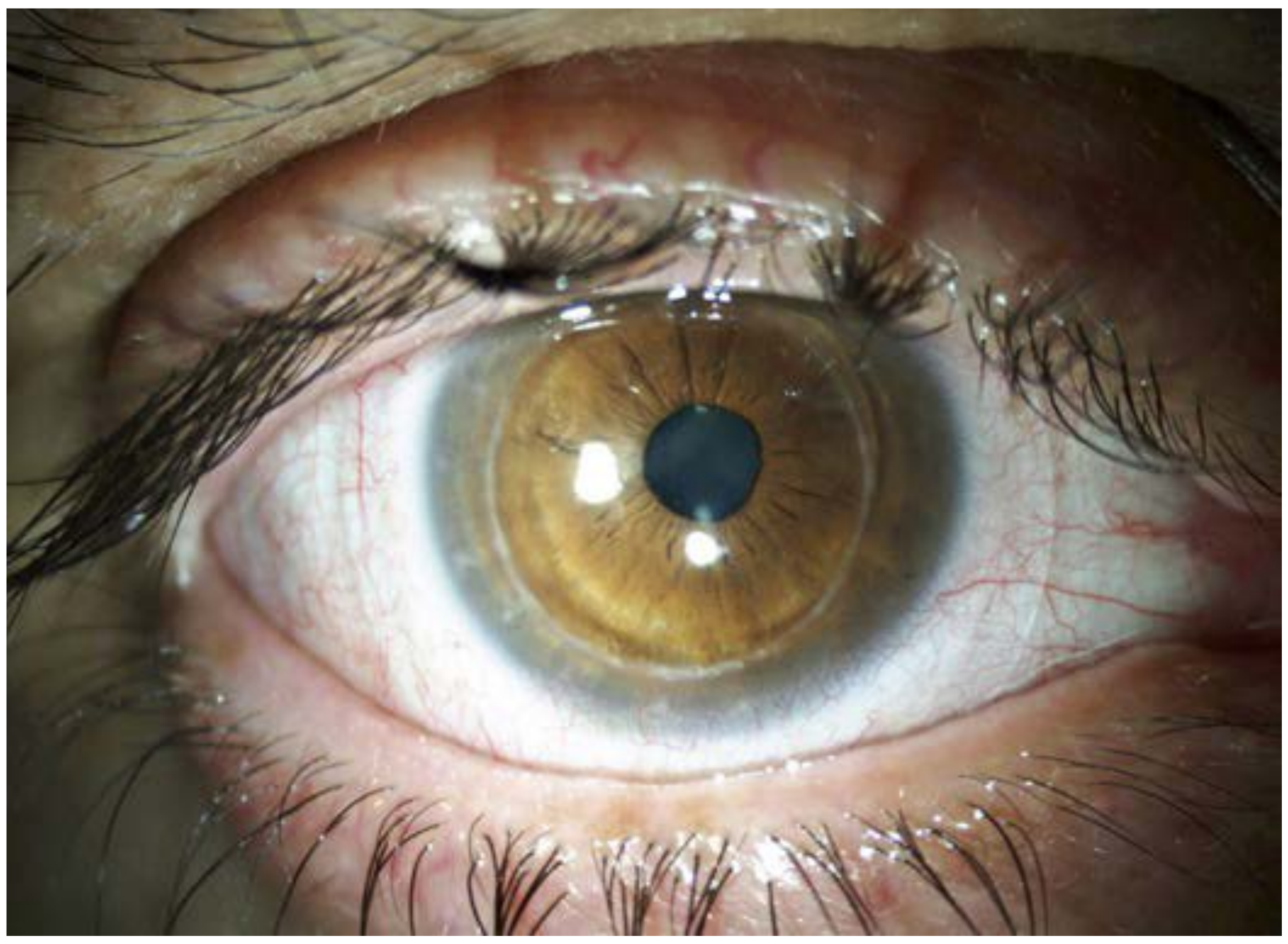

Fig. 31.13 Scleral GP contact lens with good mechanical fit on an eye with a PKP for keratoconus. Note conjunctiva is clear and neither injected nor blanched. (Photo credit: Heidi Miller, OD, CL Resident Southern California College of Optometry at the Marshall B Ketchum University, Fullerton CA.)

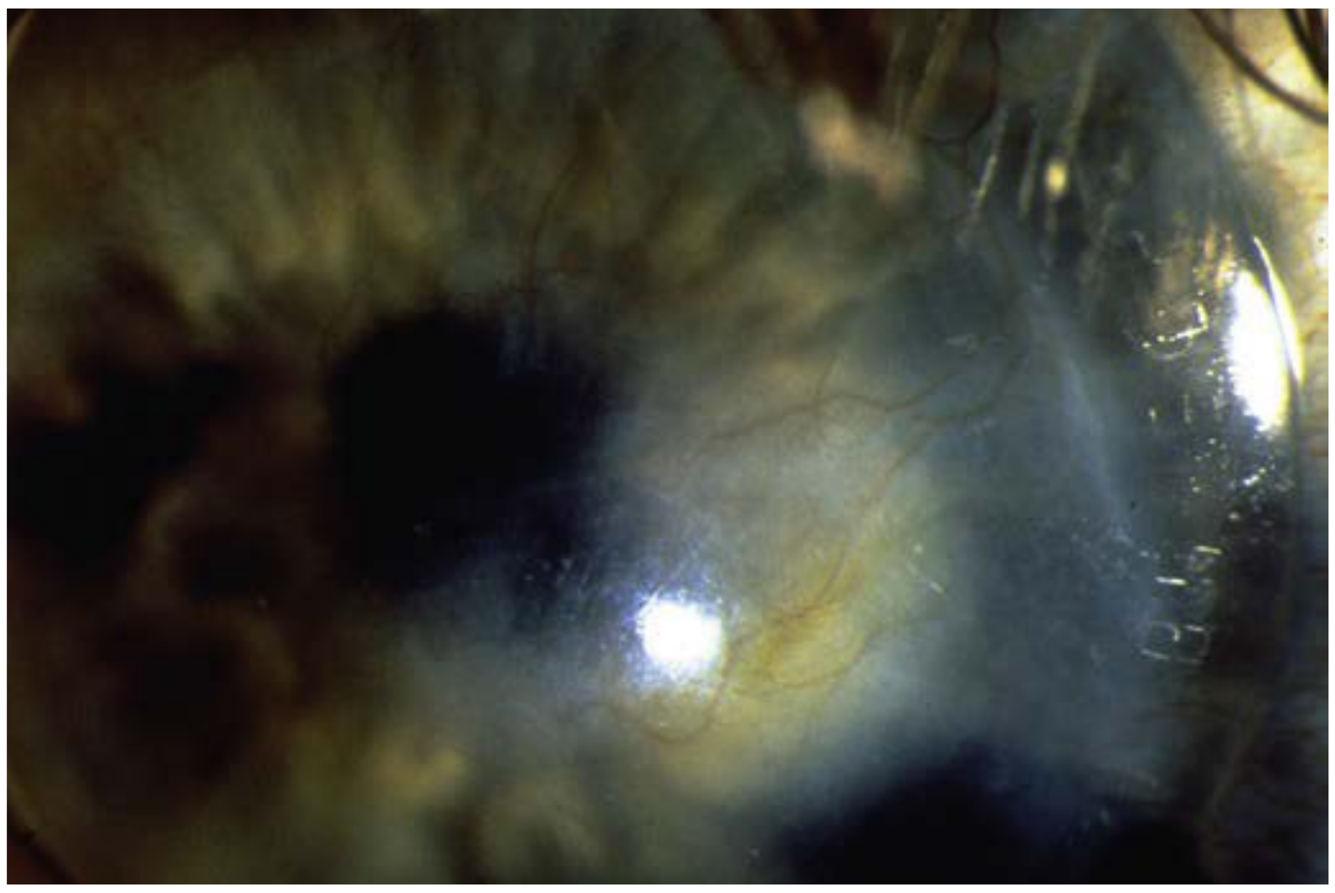

Fig. 31.14 Vascularized graft fitted with high-oxygen-transmissibility rigid lens. (Courtesy of Desmond Fonn, Bausch & Lomb Slide Library.)

apically and over the limbus, and the haptic should neither compress nor vault the scleral conjunctiva excessively except in isolated areas.

Continuing Care and Complications

Intraoperative and immediate postsurgery complications are not part of contact lens management and therefore are beyond the scope of this chapter. It is important to mention, however, that non-healing epithelial defects in the immediate postoperative period are sometimes managed with bandage hydrogel lenses used for extended wear, but only for overall time periods of a few days to a few weeks (see Fig. 31.10).

The clinician who follows post-KP patients wearing contact lenses must be constantly vigilant for non-lens-related complications as well as pathology directly related to lens wear. Any complication can increase the risk of graft rejection and/or failure. Increased intraocular pressure, leading to glaucomatous damage to the corneal endothelium as well as the optic nerve – whether surgically induced or as a steroid response – is a good example (Foulks, 1987). Similarly, phakic PKP patients, especially those who are older, often suffer cataract within 5 years of surgery (Martin et al., 1994).

Usual complications encountered in the care of post-PKP patients include:

- microbial infection – sometimes associated with contact lens wear (in particular extended wear), corneal exposure, steroid use or loose/exposed sutures (Tseng and Ling, 1995)
- corneal neovascularization – related to sutures, previous eye disease (e.g. blepharitis), large grafts, inflammation or contact lens wear (especially low-oxygen-transmissible and/or tight lenses and/or used on extended wear), probably potentiated by hypoxia or mechanical issues (Lemp, 1980; Dana et al., 1995; Adesina et al., 2013) (see Fig. 31.14)
- loose/exposed sutures – which can lead to localized abscesses and/or neovascularization, possibly induced by trauma during lens insertion/removals
- wound dehiscence – which can occur even years after successful KP, and may occur spontaneously, following suture removal or even accidentally from trauma (e.g. associated with the use of mechanical contact lens removal devices [Ingraham et al., 1998])
- epithelial staining, abrasions or defects – which may or may not be related to contact lens wear
- papillary conjunctivitis – a common contact lens complication, but also associated with exposed sutures and corneal scars
- retinal detachment – Aiello et al. (1993) found an almost 2% risk of detachment 2 years post-PKP in a cohort of 40 000 medical insurance recipients in the USA between 1984 and 1987
- uncontrolled glaucoma – typically surgically induced or a response to the use of steroids.

Graft Rejection and Failure

The clinician following post-corneal-graft patients for contact lens care must always be specifically alert for graft rejection and/or failure as well as other problems in both asymptomatic as well as symptomatic individuals. Symptoms of graft immunological rejection include any ocular inflammation, 'red eyes', pain and photophobia, but while early rejection may be symptom free (Kamp et al., 1995), an alert clinician may note one or more of the clinical signs discussed below.

Graft rejection can be epithelial, stromal or endothelial (Alldredge and Krachmer, 1981; Adesina et al., 2013).

EPITHELIAL REJECTION

Epithelial rejection appears as an elevated, undulating line that stains with fluorescein (Fig. 31.15). The line represents a zone of donor epithelial destruction by leukocytes, and, if left untreated, will march across the surface of the graft over several days or weeks. Although dramatic in appearance, epithelial rejection is not usually a major problem; the end result is the replacement of the donor epithelium by that of the host. Nevertheless, epithelial rejection should be managed with aggressive steroid treatment to decrease ocular inflammation, which may precipitate a secondary full-thickness rejection.

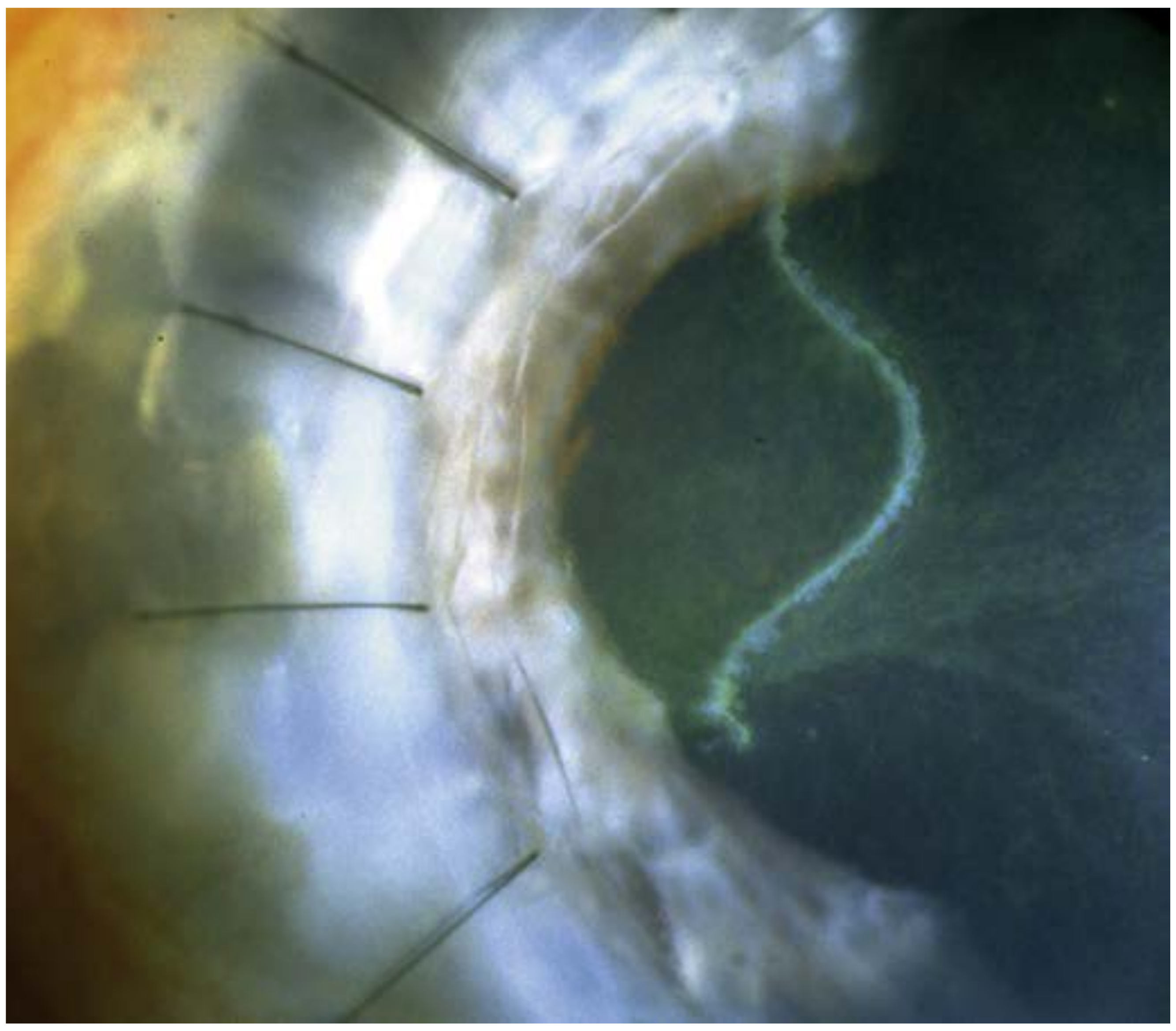

Fig. 31.15 Vertical epithelial rejection line in a graft cornea stained with fluorescein. (Courtesy of J. McCormick (Bausch & Lomb Slide Library.)

STROMAL REJECTION

Stromal rejection is seen as patchy subepithelial infiltrates, similar to those seen in epidemic keratoconjunctivitis (Krachmer and Alldredge, 1978), and/or full-thickness corneal swelling and haze, usually associated with circumlimbal hyperaemia.

ENDOTHELIAL REJECTION

A Khodadoust line and/or keratic precipitates are signs of endothelial rejection and will undoubtedly lead to an opaque cornea unless treated aggressively.

Anterior-chamber inflammation, indicated by the appearance of flare and cells, is another clinical sign of graft rejection.

The risk of rejection is believed to increase with the following:

- any corneal neovascularization, but particularly deep stromal neovascularization, especially through the graft–host interface
- any ocular inflammation
- glaucoma
- certain diseases, such as active herpetic keratitis
- each subsequent corneal graft (when the patient undergoes multiple operations).

While Smiddy et al. (1992) suggested that rigid wear by itself does not increase the risk of rejection, Gomes et al. (1996) observed many complications in a series of 18 post-PKP patients fitted with rigid lenses. Problems observed over a 3-year period following surgery included corneal staining (8 cases), neovascularization (6 cases), graft rejection episodes (5 cases), papillary conjunctivitis (3 cases) and suture-related infiltrates (2 cases).

GRAFT FAILURE

Graft failure (as distinct from immunological graft rejection), believed to represent the result of primary or secondary (e.g. glaucoma) endothelial decompensation, must also be considered. Failure can occur early or late, and may be the diagnosis when graft stromal oedema is seen without inflammation. Suspected graft failure should initially be treated with anti-inflammatory drugs (e.g. steroids) in case the diagnosis is really rejection, which may enable the KP to be saved.

Thompson et al. (2003) report an overall PKP survival rate of about 88% at 5 and 80% at 10 years postoperatively in a very large series (3992 consecutive eyes), with the highest risk of failure or rejection (about 4%) within the first 2 years but continuing at about 2% per year up through the 10-year point. PKPs for keratoconus had the best survival rates, but endothelial failure was common for corneas grafted for pseudophakic bullous keratopathy and regrafts also had lower survival rates.

Other Management Issues

Several studies suggested that PKP topography changes with rigid wear, with the graft becoming both flatter and smoother (less astigmatic) (Manabe et al., 1986; Wilson et al., 1992; Sperber et al., 1995). De Toledo et al. (2003), Szczotka-Flynn et al. (2004) and Lim et al. (2004), however, found increasing astigmatism with long-term follow-up of PKP for keratoconus, possibly owing to keratoconus progression in the remaining host corneal (rim) tissue. Recurrent ectasia has been found in corneal grafts and is diagnosed on average two decades after the initial PK (Patel et al., 2009). Hayashi and Hayashi (2006), on the other hand, found relative stability in corneal surface videotopography of 130 consecutive PKPs for a variety of diseases (31% keratoconus) studied with Fourier series analysis.

Corneal endothelial changes over time are not believed to be different from those expected of any PKP cornea without lens wear (Speaker et al., 1991; Bourne and Shearer, 1995). Graft epithelial barrier function is maintained with post-PKP rigid lens wear (Boot et al., 1991).

Collateral problems commonly encountered include blepharitis, meibomian gland dysfunction and dry eyes associated with acne rosacea or poor lid apposition. These conditions need to be managed aggressively with lid hygiene, artificial tears (preferably unpreserved and unit dose) or appropriate pulsed antibiotic treatment (both local and systemic). Additional surgery may be required, such as punctal occlusion or blepharoplasty. In general, strenuous efforts must be made to protect the graft from drying and to suppress inflammation, in order to avoid rejection episodes.

Dilated and fixed pupils are occasionally a sequela of intraocular surgery (Urrets-Zavalia syndrome; Tuft and Buckley, 1997), but usually do not pose any problems with respect to contact lens wear. Such patients rarely may benefit from an artificial pupil contact lens, but often this is more for cosmetic than for visual reasons.

Contact Lens Results

Most trephine-cut post-PKP patients benefit optically from rigid contact lens wear (Ruben and Colbrook, 1979; Lass et al., 1990; Smiddy et al., 1992; Silbiger et al., 1996; Wietharn and Driebe, 2004; Geerards et al., 2006).

Ho et al. (1999) studied 40 post-PKP eyes (compared with 40 control eyes) and found that post-PKP eyes were more complex and time consuming to fit successfully with rigid lenses than were 'normal' eyes, requiring more diagnostic contact lenses, more ordered contact lenses and more office visits than did control eyes. Contact lens wear success rate and complication rates (both lens and graft related), however, were not significantly different between the two groups of eyes.

Conclusion

Over the past century, both PKP and various types of LK have become accepted and frequently used surgical treatments for many corneal diseases. Although techniques remained relatively stable during the second half of the 20th century, the last few years have seen the introduction of a set of new techniques, many of which hold promise for major improvements in outcomes and increased utilization. Sutton et al. (2008) found that only 5.3% of patients required a rigid contact lens following KP for keratoconus. All others were able to attain at least 6/12 best corrected visual acuity 6 months postoperatively.

Nonetheless, for the near term, the anterior corneal surface commonly remains distorted following many corneal grafts, particularly PKP, and therefore patients often continue to benefit significantly from the optical enhancement afforded by the use of contact lenses – rigid lenses in particular. There are many potential post-corneal-graft complications, including corneal neovascularization, loose/exposed sutures, glaucoma, cataract, wound dehiscence, microbial infection, graft failure and rejection, and retinal detachment. The use of contact lenses can provoke additional complications, including enhanced risk of corneal neovascularization, loose/exposed sutures, wound dehiscence, epithelial defects, giant papillary conjunctivitis and other inflammatory conditions, and microbial infection. Many of these problems may potentiate graft rejection and/or failure. The risk/benefit ratio must therefore be considered carefully in each individual case, and professional supervision should occur at reasonable intervals, perhaps every 3–4 months, even in asymptomatic individuals.

In conclusion, Williams et al. (1991), reporting on 60 patients wearing contact lenses for more than 2 years following PKP, found that the majority (75%) were 'satisfied' with their outcomes, but those who were dissatisfied complained of both contact lens and graft problems.

Access the complete references list online at http://www.expertconsult.com.

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32

Orthokeratology

PAUL GIFFORD

Introduction

For a multitude of reasons, many patients want to be able to see well and to function without the need for a refractive correction by glasses or contact lenses. The popularity of refractive surgery procedures with some patients is a clear indicator of that desire. Orthokeratology (OK) is one other manifestation of the ongoing attempts to meet this need. The fact that the cornea is the major optical contributor to the power of the eye, and is also the most accessible of the refractive elements of the eye, has made OK an obvious candidate for initiating refractive control.

It has long been known that the cornea can be deformed by the application of an external pressure, whether an acute pressure as in applanation tonometry or a more sustained pressure from wearing rigid contact lenses. Early studies on the wearing of polymethyl methacrylate (PMMA) lenses demonstrated that they can induce changes in corneal curvature, refractive error and visual acuity. The corneal changes were typically a central flattening, which often took weeks to return to normal. Corneal shape changes have also been demonstrated with the wearing of rigid gas-permeable contact lenses. In general, these changes include a reduction in corneal toricity and a tendency for the cornea to change from its normal aspheric shape to a more spherical one.

These corneal shape changes, when occurring in routine contact lens fittings, are normally considered an undesirable side-effect of a non-optimal lens fit. However, Jessen (1962) proposed the exploitation of this effect so as to induce useful corneal shape changes to eliminate, or at least reduce, myopic refractive errors.

Although early OK procedures garnered some support, the lack of verifiable evidence on its clinical efficacy precluded general acceptance. However, more recently the use of new innovative lens designs has given renewed impetus and interest in this technique.

History of Orthokeratology

OK was first described by Jessen (1962) whereby rigid contact lenses could be used to correct ametropia through altering corneal curvature. Jessen described how rigid lenses, then manufactured in polymethyl methacrylate (PMMA), could be fitted steeper than corneal curvature to induce corneal steepening so as to correct hyperopia, or flatter than corneal curvature so as to flatten the cornea and correct myopia. Lenses were fitted with sufficient difference in curvature to the cornea to promote change in corneal curvature, but not so great as to destabilize lens fitting. Lenses were then worn during waking hours and progressively altered in curvature as corneal shape changed until the full refractive effect was achieved, at which stage daytime wear was continued with the final fit lens to retain the effect.

In this format, OK remained a niche procedure practised by a small number of dedicated enthusiasts. Early clinical reports indicate that outcomes were variable, with no consensus on the most appropriate lens design, or on the number and timing of lens refittings (Carney, 1994). The first comprehensive study was conducted by Kerns (1976, 1978), with further studies reported by Binder et al. (1980) and Polse et al. (1983). Although the experimental design and breadth of these studies varied, they nevertheless were reasonably consistent in their overall findings. As a result of those controlled clinical studies, it was established that the refractive effect was unpredictable, variable and slow. Regression was rapid so ongoing lens wear was required to retain effect, and there was a tendency to induce significant corneal astigmatism if lens centration was not controlled.

Modern Orthokeratology

The mid 1990s saw convergence of three independent technologies that revolutionized OK. Computerization led to greater control over lens lathing and dramatically improved measurement of corneal topography, while improvements to polymer technology saw the introduction of gas-permeable contact lens materials.

Independently of each other, Wlodyga and Bryla (1989) and Harris and Stoyan (1992) reported that reverse-geometry lens designs, now made possible through computerized lathing, could be utilized to stabilize flat-fitting lenses. Reverse-geometry lenses have secondary curves that are steeper than the back optic zone radius (BOZR) (Fig. 32.1). When utilized in a flat-fitting rigid contact lens, this enables peripheral realignment with the cornea in what would otherwise be a poor-fitting lens with excessive edge lift. When applied to OK this meant that larger steps in lens flattening could be made between successive lenses without compromising fit and centration. This new approach in OK lens fitting was given the name 'accelerated orthokeratology' because it provided rapid onset (within a few days) of effects that had previously taken weeks or months to achieve.

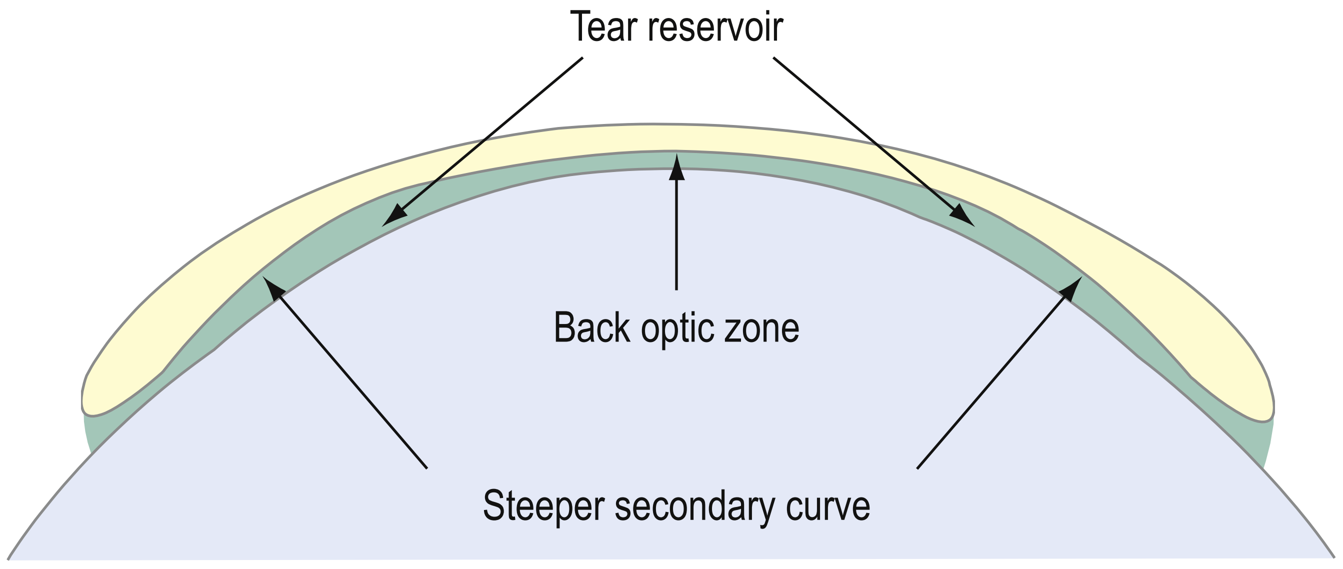

Fig. 32.1 Reverse-geometry lens design, showing the steeper secondary curve and related tear reservoir.

Overnight Orthokeratology

In the early days of accelerated OK, lenses were still prescribed to be worn during waking hours, and when full refractive effect was achieved then wear of the final 'retaining' lens was reduced to the smallest amount of time that maintained the refractive effect. Although this meant that patients benefited from some waking hours free from vision correction, they were still inconvenienced by having to wear their OK lenses at some point during the day. Meanwhile gas-permeable lens materials had continued to evolve, with overnight wear of conventional rigid gas-permeable lenses achieving USA Food and Drug Administration (FDA) approval in 1986.

The first suggestion of overnight lens wear in OK was made by Harris and Stoyan (1992,) who proposed the traditional OK approach of daily lens wear until the retainer stage was reached. At this stage, lenses with oxygen transmissibility sufficient to allow extended wear could be worn during sleep for three to six nights per week, with the lenses removed on waking. Grant (1992) reported that OK could instead be conducted from the outset solely through overnight lens wear with no lens wear required during the day. Overnight wear has since become the accepted modality for OK, with FDA approval for overnight wear of the Paragon CRT lens for OK (Paragon Vision Sciences, Mesa, AZ, USA) first issued in 2002.

How Orthokeratology Works

The original concept of OK was based on the belief that non-alignment fitted rigid lenses would bend the cornea to flatten or steepen curvature to reduce levels of myopia or hyperopia, respectively. There is now good evidence that the corneal changes with reverse-geometry lenses are more complex than a mechanical bending of the cornea. Swarbrick et al. (1998) reported results of measurements of corneal shape and thickness changes after OK lens wear. They demonstrated that the myopia reduction was accompanied by a flattening of the central cornea, thinning of the central cornea and thickening of the mid-peripheral cornea. By using Munnerlyns' formula for calculating laser refractive surgery ablation depth, the authors were able to show a close correlation between the predicted refractive change from change to central corneal thickness and actual refractive change.

Using optical pachometry, Alharbi and Swarbrick (2003) revealed that whereas central corneal thinning was mostly attributed to changes in epithelial thickness, the mid-peripheral thickening was mostly a stromal effect. It has been suggested that cell compression, rather than cell movement or loss, may be the primary mechanism of central epithelial changes (Choo et al., 2004). Further research has shown that stromal, but not epithelial, thickness changes during overnight wear of OK lenses are related to oxygen transmissibility of the lenses (Haque et al., 2007). There is conjecture on whether OK influences posterior corneal curvature. Mild posterior corneal curvature changes were found by Owens et al. (2004), which would suggest that corneal bending does have some role in the mechanism of change. However, using a Pentacam analysis system, Tsukiyama et al. (2008) showed instead that overnight OK lens wear alters the anterior corneal shape rather than the posterior corneal curvature or the anterior-chamber depth.

The mechanism by which OK creates changes to corneal curvature, thickness and refraction is not understood. Intuition suggests that OK lenses impose a direct moulding effect on the corneal surface through eyelid pressure. Mountford (1997) has put forward an alternative hypothesis: that it is the tear reservoir generated by the steeper secondary curves that primarily leads to the pressure changes in the post-lens tear film that is responsible for the corneal tissue redistribution.

Outcomes of Accelerated Orthokeratology

The outcomes of accelerated OK can be measured with respect to the efficacy of the technique, the extent and time course of regression after lens removal, changes to corneal physiology, and safety.

EFFICACY

The efficacy of the use of reverse-geometry lenses, worn in both daily wear and overnight wear protocols, has been evaluated in a number of recent studies, examples of which are given here.

Swarbrick et al. (1998) fitted reverse-geometry lenses (OK74; Contex) manufactured in Airperm material to 6 young myopic subjects. The lenses were worn on a daily-wear basis for 28 days, and resulted in a myopia reduction of 1.71 ± 0.59 D. Lui and Edwards (2000) conducted a 100-day daily-wear trial on 14 subjects, again using the OK74 design in Airperm material. They reported a myopic reduction of 1.50 ± 0.45 D. Nichols et al. (2000) conducted a 60-day trial on overnight wear of the same Contex OK lenses, with 8 subjects completing the study. The reduction in subjective refraction 4 hours after awakening was 1.83 ± 1.23 D. Using Paragon CRT lenses, Bernsten et al. (2005) found a reduction in myopia of 3.33 ± 0.96 D after 1 month of overnight lens wear.

These studies are reasonably consistent in their estimation of the magnitude of refractive change, and in the variability of the response. While correction of greater amounts of myopia is sometimes reported, and proposed by some OK lens designers, they are not what is to be expected in the repeatable application of current lenses.

Changes in corneal curvature and shape have also been evaluated in many studies, although differing techniques have been employed. Swarbrick et al. (1998), using the EyeSys corneal topographic mapping system, found that the apical corneal power diminished by 1.19 ± 0.38 D. Over the central 5–6 mm zone of the cornea there was significant central corneal flattening, which diminished towards the mid periphery. Lui and Edwards (2000) used keratometry and the TMS-1 videokeratographer to report central corneal flattening of 0.14 ± 0.06 mm vertically and 0.12 ± 0.07 mm horizontally. Nichols et al. (2000), using a Humphrey Atlas topographer and an Orbscan slit scan topographer, reported a significant flattening of the apical radius of 0.20 ± 0.90 mm, that again diminished towards the periphery.

In general then, it is well established that changes in corneal shape and refractive error can be induced by reverse-geometry lenses, and that the changes occur more rapidly than with earlier lens designs, with significant structural and optical change in as little as 15 minutes (Lu et al., 2008). On average, 75% of the required refractive change is achieved with 1 night of lens wear with an end-point achieved within 7–10 nights of lens

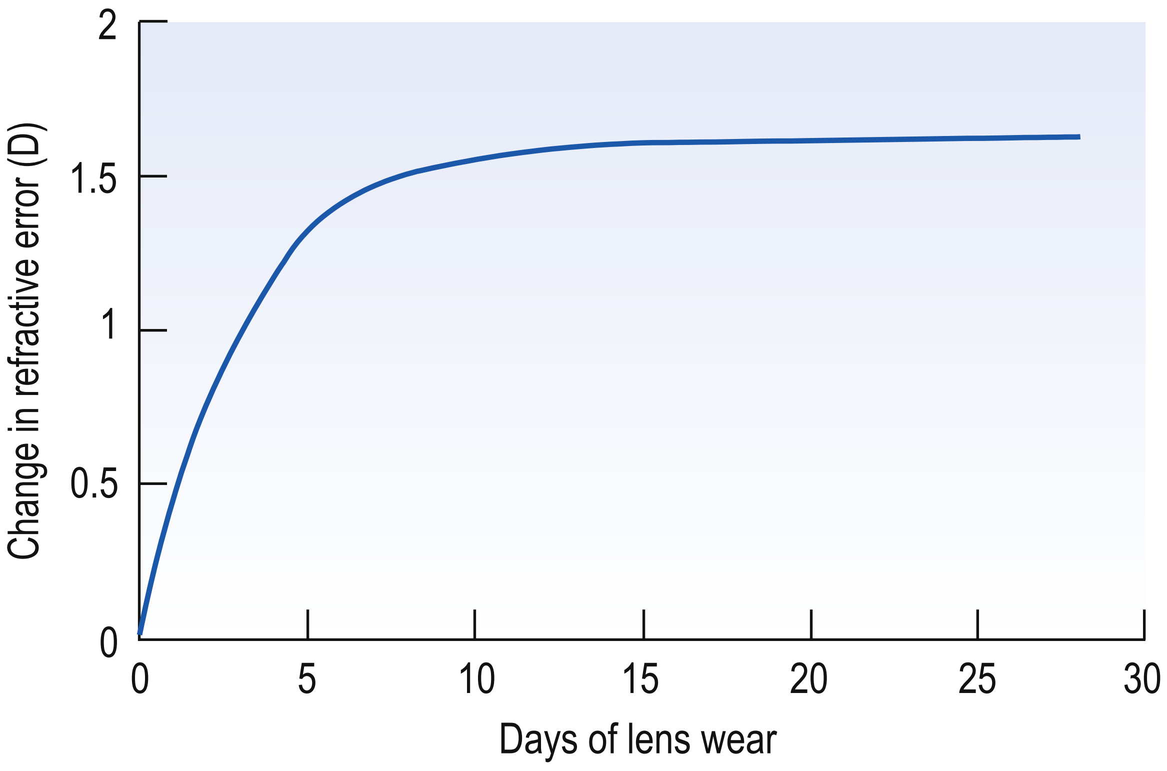

Fig. 32.2 Model of the expected refractive change and its time course during wear of reverse-geometry lenses.

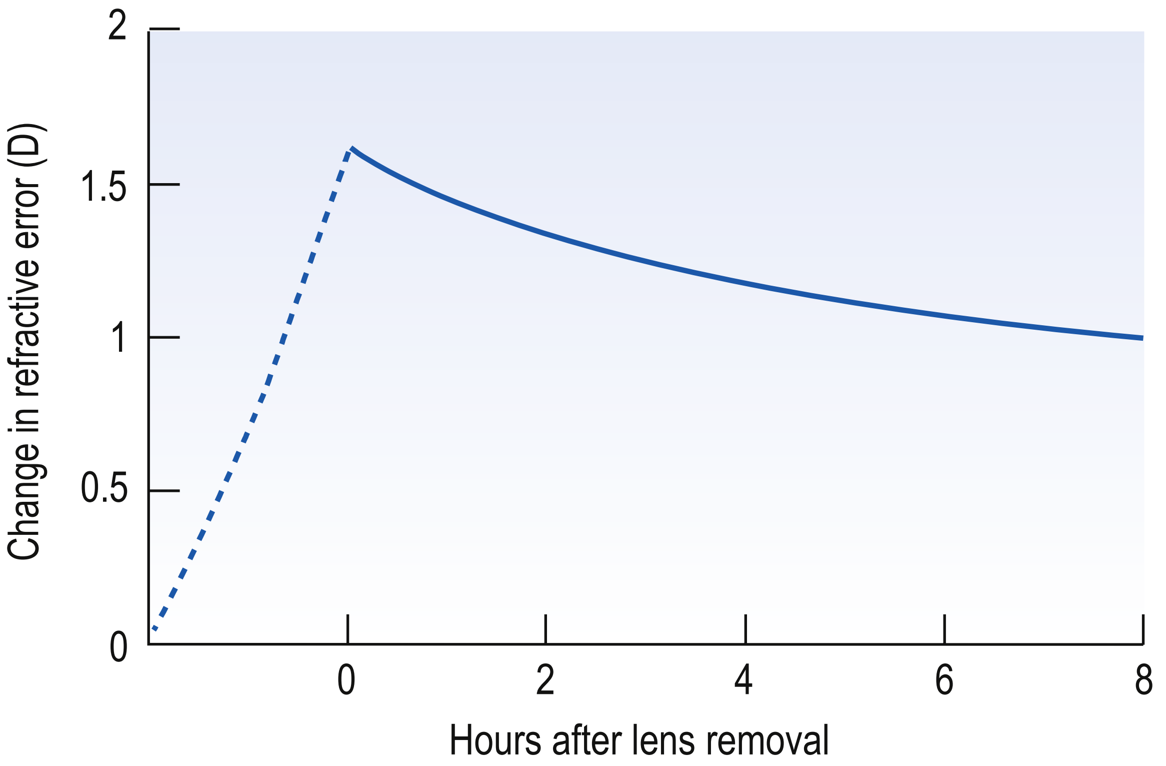

Fig. 32.3 Model of the expected regression of refractive change during waking hours after overnight wear of reverse-geometry lenses.

wear (Swarbrick, 2006). A model of the average induced refractive change from these reported studies, and its time course, is shown in Fig. 32.2.

Although corneal irregularities such as a decentred treatment zone are sometimes encountered, in general the corneal changes do not lead to losses of high-contrast visual acuity, low-contrast visual acuity or contrast sensitivity for these experimentally repeatable magnitudes of treatment (Johnson et al., 2007).

REGRESSION

An appealing factor of OK is that changes to refractive effect and corneal curvature return to pre-leans-wearing values if wear is ceased; however, this regression of effect starts soon after lens removal so that some unwanted loss of refractive effect is observed during the day between wearing intervals (Fig. 32.3).

Mountford (1998), in a retrospective study of 48 patients, found that after 90 days of overnight wear the regression of apical corneal power over approximately an 8-hour period stabilized between 0.50 and 0.75 D per day, but with significant individual variation. Nichols et al. (2000) concluded from their study that the refractive outcomes after 60 days of overnight wear were sustained over an 8-hour day. However, analysis of their findings shows that most changes were measured over only a 4-hour period, and some changes – as indicated by autorefraction data – did show regression up to 0.50 D (Efron, 2000). On average, a regression of approximately 0.25–0.75 D is expected throughout the day after overnight lens wear, but this regression is greater in the early stages of OK lens use. Up to 90% of recovery towards the baseline refraction can be expected within 72 hours of lens discontinuation (Barr et al., 2004).

CORRELATIONS

The relationship between refractive changes and corneal curvature changes has been a matter of some conjecture. Numerous studies using early OK lens designs reported that the refractive change was greater than that expected from corneal power changes measured using keratometry. The reported ratio of these changes was often 2 : 1 or more.

This anomaly is most likely a consequence of the irregular nature of the induced corneal topographic changes. It is now apparent that the corneal shape changes are more marked in the central cornea, and diminish towards the mid periphery (Swarbrick et al., 1998), and hence keratometry results are somewhat unreliable. Similarly, the reported vision improvements were often greater than would be predicted from corneal curvature changes. As well as the above explanation, these vision reports were influenced by a lack of standardization of testing procedures, practice effects from repeated vision testing (McMonnies, 2001) and bias from the unmasked protocols often used (Carney, 1994).

Difficulties with correlating corneal curvature, refraction and vision were confirmed by Nichols et al. (2000) using overnight wear of reverse-geometry lenses. Refraction was measured both subjectively and by autorefractor, with a larger reduction in myopia reported for subjective refraction than for autorefraction. The authors hypothesize that this finding is a consequence of the greater weight given to peripheral optical effects with autorefraction.

CORNEAL PHYSIOLOGY

Lum and Swarbrick (2007) reported the appearance of fibrillary lines in the anterior stroma of a 29-year-old Asian woman after wearing overnight OK lenses for approximately 9 years. The fibrillary lines were fine, slightly curved and subepithelial, and were arranged in a band-like annulus in the corneal mid periphery. The lines were not associated with epithelial staining, although a marked Fischer–Schweitzer corneal mosaic was noted after blinking. Fibrillary lines are a relatively common finding in normal and keratoconic corneas and have been reported previously accompanying OK lens wear. Lum et al. (2012) went on to map the corneal subbasal nerve plexus (SBNP) for this patient using confocal microscopy to establish that the earlier reported fibrillary lines were the visible appearance of alterations to the SBNP induced by OK lens wear. The SBNP was also mapped for a 21-year-old Asian woman wearing OK lenses for approximately 1 year and a non-OK-lens-wearing 28-year-old Asian woman, to reveal that the SBNP took on a whorl pattern appearance in the OK-lens wearer, compared with a tortuous network of central nerve fibres and thicker curvilinear mid-peripheral fibres in the non-OK-lens wearer.

Following on from their earlier work, Lum et al. (2014) using confocal microscopy measured corneal nerve fibre density (NFD) over a 1 mm^2 area in OK-lens-wearing subjects and also looked at changes to corneal sensitivity. The study, involving 16 subjects, revealed a significant reduction in central NFD after 3 months of lens wear that improved but did not return to pre-lens-wearing values 90 days after lens wear was ceased. Corneal sensitivity was similarly reduced, but in this case returned to pre-lens-wearing levels within 30 days of discontinuation of wear.

It is clear from this research that OK lens wear alters corneal nerve structure and that corneal sensitivity is reduced, after as little as 1 night (Lum et al., 2013). However, there are currently no published studies to report on whether soft or rigid contact lens wear similarly alters corneal nerve structure. The limited current evidence suggests that in OK these changes begin to resolve once lens wear is ceased, leading to recovery of corneal sensitivity over the short term, and corneal nerve morphology returns towards pre-lens-wearing values over the longer term.

SAFETY

Corneal complications can occur in OK, as in any form of contact lens wear. For example, corneal staining can be present, particularly after overnight lens wear. The significance of epithelial thinning, as reported after wear of reverse-geometry lenses, in the occurrence of serious complications remains to be established (Swarbrick et al., 1998). Overnight wear of any contact lens has previously been shown to be a major risk factor for keratitis (Holden and Lazon de la Jara, 2007), so the finding of complications in OK is perhaps not unexpected. Furthermore, OK lenses have been shown to retain more bacteria than alignment-fit rigid lenses after bacteria-loaded overnight lens wear (Choo et al., 2009), which may increase the risk for an infection in OK patients if suitable conditions are present.

Watt and Swarbrick (2007) investigated trends in microbial keratitis (MK) associated with OK by performing a meta-analysis of cases that were reported in ophthalmic journals or presented at conferences; 123 cases were reported from 2001 to 2007. Most cases were found to be in female, East Asians aged between 8 and 15 years. In 41 (33%) of the cases Acanthamoeba was implicated as the causative organism, and Pseudomonas aeruginosa in 46 (36%) cases. Their analysis revealed a peak of cases in East Asia, particularly in China and Taiwan during a short period when regulation of the modality was limited. Acanthamoeba keratitis in OK has been shown to be related to the use of tap water for rinsing (Lee et al., 2007), so the simple act of avoiding tap water could well have prevented a large number of the cases that Watt and Swarbrick assessed.

In Australia, Watt et al. (2007) sent a questionnaire to members of the Orthokeratology Society of Australia (now the Orthokeratology Society of Oceania, OSO) and received a response from 33 optometrists who had been fitting OK lenses for a median period of 7.5 years. OSO membership requires completion of an accredited certification course for OK. The authors combined their findings with two previously reported cases to reveal nine cases of MK (4 P. aeruginosa; 2 Acanthamoeba spp.; 3 unknown organism). Poor patient compliance was implicated in most cases of presumed MK in OK. Although speculative, the low magnitude of reported cases, particularly those involving Acanthamoeba, suggests that better regulation of OK lens fitting is beneficial in reducing rate of infection.

More recently, Bullimore et al. (2013) investigated the risk of MK with overnight OK by asking randomly selected practitioners to report cases of patients who attended for unscheduled visits for a painful red eye. From the 1317 (640 adults; 677 children) patients that were ultimately sampled, eight events of corneal infiltrates associated with a painful red eye were reported (2 adult; 6 children). Two of these, both occurring in children, were classified as MK but did not result in loss of visual acuity. The overall estimated incidence of MK established by their study was 7.7 per 10 000 years of wear overall, and 13.9 per 10 000 years of wear in children, leading the authors to conclude that the risk of MK with overnight OK is similar to that with other overnight-wearing modalities. By comparison, Stapleton et al. (2008) investigated cases of MK presenting in Australia over a 12-month period to report an incidence of 19.5 cases of MK per 10 000 years of overnight wear of soft contact lenses, and 25.4 cases of MK per 10 000 years in overnight wear of silicone hydrogel soft contact lenses.

Although these studies suggest that overnight OK offers no greater risk than does traditional overnight lens wear, accurate information on the prevalence of serious complications in OK is still not available, and the potential for their occurrence must be recognized and protected against (Van Meter et al., 2008). To this end, Cho et al. (2008) provided a comprehensive guideline for practitioners to improve their OK practice and minimize unnecessary or preventable complications as they believe that the key to safe OK lens wear is to update knowledge in the field continually, and to practise to the highest professional standards.

DETERMINANTS OF SUCCESS

A drawback to the more general acceptance of OK has been the variability of responses and lack of predictability. Although a number of ocular and contact lens characteristics have been proposed as candidates for influencing the refractive outcome, there have been no conclusive findings.

Carkeet et al. (1995) carried out an analysis of a range of ocular characteristics, including subjective refraction, corneal thickness profile, intraocular pressure, ocular rigidity and epithelial rigidity. The only significant finding was that OK success was related to the prefitting refractive error, with higher levels of myopia leading to reduced refractive change. Studies on corneal hysteresis and corneal resistance to deformation have failed to identify reliable and consistent effects of corneal biomechanics on OK outcomes (Chen et al., 2009; Gonzalez-Meijome et al., 2008).

The ocular characteristic most accepted as being of significance to the induced refractive change is the prefitting corneal shape. Mountford (1997) and others maintain that the practical limit of OK is defined by the corneal asphericity, as further corneal change is unlikely when the cornea achieves a spherical shape. A regression analysis of change in apical corneal power and initial corneal eccentricity directly related the induced corneal (and hence) refractive change to corneal shape. Near-spherical corneal shapes led to very little corneal power change (Mountford, 1997).

Hyperopic Orthokeratology

OK was first described by Jessen (1962) as a technique to correct hyperopia, through steepening the corneal profile using steep-fitting rigid lenses, but this approach never gained traction, probably because lens materials of the time induced significant corneal oedema (Coon, 1982). Correcting myopia has since been the main focus of OK lens manufacturers; however, in recent years there has been growing interest in correcting hyperopia, with a number of lens manufacturers now offering OK designs to correct hyperopia and presbyopia.

To correct hyperopia requires central corneal steepening, which it has been shown to be possible to achieve with 4 hours wear of steep-fitting rigid lenses fitted with apical clearance (Swarbrick et al., 2004) and overnight wear of specifically designed hyperopic OK lenses (Lu et al., 2007a). It has since been shown that the time course of refractive and corneal topography change in hyperopic OK is analogous to that in myopic OK, with most effect occurring after the first night of wear and regression of effect during the day (Gifford and Swarbrick, 2008). Full targeted effect and greater retention of effect during the day is achieved within 1 week of wear. Haque et al. (2008) measured changes to corneal thickness using optical coherence tomography to reveal that hyperopic OK caused an increase in central epithelial thickness. Gifford et al. (2011), using optical pachometry, found that hyperopic OK did not alter central corneal epithelial thickness but instead thinned the mid-peripheral epithelium. Their outcomes from an earlier study (Gifford et al., 2009) suggest that the mechanism of mid-peripheral epithelial thinning is corneal compression by the lens in the paracentral region, as opposed to central post-lens tear film forces.

These corneal steepening effects seem to be more difficult to induce and control compared with central corneal flattening. In particular, the treatment zone size in hyperopic OK is reported to be smaller in comparison with that in myopic OK (Gifford and Swarbrick, 2009), and treatment outcomes are reported to be more variable when targeting higher (+3.50 D) compared with lower (+1.50 D) levels of refractive correction (Gifford and Swarbrick, 2008). Although corneal steepening changes can be produced, clinical results so far have not been compelling (Swarbrick et al., 2004; Lu et al., 2007a). On the positive front, hyperopic OK has been shown to offer a viable technique for providing monovision correction in emmetropic presbyopes (Gifford and Swarbrick, 2013).

Orthokeratology Lens Fitting

There are numerous OK lens designs, each with different approaches to lens fitting, which makes this an extensive subject to cover in a small space. Rather than describe all of these approaches, this section instead offers an overview of the principles of myopic OK lenses that are common to all designs.

INDICATIONS AND CONTRAINDICATIONS

Patient selection is just as important as for other contact lens fittings. However, in addition to the usual considerations, it is essential that realistic expectations are established with prospective patients, about the magnitude of the expected improvement in unaided acuity, and potential limitations on its stability. Patients need to be comfortable that continued overnight lens wear is a requirement and be able to make an informed choice considering the risks that overnight wear introduces compared with alternative contact lens modalities.

The usually accepted upper refractive error limit is 4.50 D of myopia, and 1.50 D of with-the-rule corneal toricity. Higher levels of myopic correction are achievable, and indeed advertised by some OK lens manufacturers; however, overall treatment zone (TZ) diameter reduces with higher amounts of refractive change (Lu et al., 2007b). In cases where the pupil diameter exceeds the TZ diameter, visual halos or flare may be reported. TZ diameter also varies between individuals and needs to be taken into particular consideration for patients with large pupils in standard illumination. As with other lens fittings, good ocular health and the ability to handle and maintain the lenses are expected.

Perhaps most important for prospective OK candidates is their motivation, be that achieving the ability to see clearly without refractive correction during habitual hours, or more increasingly to reduce further progression of myopia. OK also offers a viable alternative to those interested in refractive surgery though not willing to undergo laser treatment. Regardless of their motivation, in reaching a decision to proceed they need to be fully aware that OK is an ongoing procedure requiring continued overnight wear of contact lenses.

BASE CURVE

The back optic radius (BOR) of the lens is fit flatter than corneal curvature to correct myopia, and steeper than corneal curvature to correct hyperopia. The orthofocus technique first published by Jessen (1962) described how the BOR should be altered from corneal curvature by an amount equivalent to the refractive change being targeted, so a −2.00 D target for a 45.00 D cornea would require fitting with a 43.00 D BOR. Most current lens designs alter BOR by slightly more than the 'Jessen factor' to accommodate what is usually described as a 'compression factor'. The compression factor varies across lens designs from 0.00 D to 1.00 D.

FITTING APPROACHES

Fitting OK lenses is based around a sagittal height fitting philosophy, with an ideal fit obtained through choosing or designing a reverse-geometry rigid contact lens that has the same sagittal height as the cornea at the peripheral bearing point of the lens. There are essentially three approaches to OK lens fitting that have been adopted by different OK lens designers:

Empirical Lens Fitting

This is the easiest approach for the practitioner as it requires sending only keratometry readings or topography image capture, alongside desired refractive change, to the lens manufacturing laboratory. The lab then uses this data to design and manufacture the calculated best-fit lens, which is returned to the practitioner.

Advantages
- Easier for novice users
- Reduced set-up costs – no trial lenses required.

Disadvantages
- Practitioner is totally reliant on the manufacturer to determine lens parameter changes.
- It takes longer to achieve a final fit owing to the time it takes the lab to manufacture and supply each lens.

Trial Lens Fitting

Trial lens fitting sets allow the practitioner to hold a small range of around 20–25 lenses that can be used to assess the fit of the lens. A computer program or table is used to predict the best fitting lens based on keratometry or corneal topography data, which is then tested in overnight trials, before settling on the best-fit lens. Once best fit is achieved the measured change in refraction against the predicted change from the trial lens can be used to accurately determine the final lens parameters.

Advantages

- Patient can immediately start overnight trials and any changes required during the fit process can again be supplied from the trial set.

Disadvantages

- Trial lenses assess lens fit only, so refractive error is not necessarily corrected.

Full Diagnostic Bank

Some lens designs are available whereby the practitioner holds stock of around 100–150 lenses, allowing lens fit to be assessed while targeting the full refractive correction. A computer program or table is used to predict the best fitting lens based on keratometry or corneal topography data and refractive error. The suggested lens is then worn for overnight trials with fit and / or targeted change in refractive error altered until optimum fit and vision correction is achieved.

Advantages

- Patient is fitted from the outset with final-fit lenses.
- Practitioner has full control over the fitting process.
- Diagnostic bank can be utilized for emergency cases (i.e. existing wearer loses or breaks a lens).

Disadvantages

- Having to hold a large number of lenses makes this the most expensive option to set up.

POST-WEAR ASSESSMENT

Standard rigid lens fit is gauged through visual assessment aided by instillation of sodium fluorescein so as to determine the optimum alignment with the cornea. This same approach can be followed to improve OK lens fit; however, it is the change to corneal curvature made by the orthokeratology lens during overnight wear that provides the most information on lens-fit efficacy. Although it is possible to select an initial OK lens from keratometry values, it is not possible to assess fitting outcome accurately without a corneal topographer, which makes corneal topography an essential component in OK lens fitting (Maldonado-Codina et al., 2005).

Modern corneal topographers offer a function to subtract post-lens-wearing maps from pre-lens-wearing maps to display a difference map. These maps use colours to determine degree of change that has occurred from the baseline map: green indicating no change, blue indicating areas of flattening, and red indicating areas of steepening.

One of the following patterns may be typically observed after overnight myopic OK lens wear:

Bull's Eye (Optimal Lens Fit)

On a tangential map, a good-fitting OK lens is indicated by a central area of 'blue' corneal flattening surrounded by an annulus of 'red' corneal steepening that is again centred on the corneal apex (Fig. 32.4A). When viewed as an axial map, the extent of the central 'blue' area defines the limits of the refractive treatment effect (Fig. 32.4B).

Smiley Face (Flat-fitting Lens)

Flat-fitting lenses typically decentre superiorly during closed-eye wear, which results in a superiorly displaced area of central flattening. The annulus of paracentral steepening is similarly displaced, giving the appearance of a smile (Fig. 32.4B).

Central Island (Steep-fitting Lens)

Steep-fitting lenses centre well, but fail to provide uniform compression at the corneal apex. The result is a small area of central corneal steepening surrounded by an annulus of flattening, a central island in what would otherwise have been a bull's eye appearance (Fig. 32.4C).

During the fitting process, corneal topography is assessed after each period of overnight wear. If a smiley face or central island is observed then the sag height of the lens is respectively increased or decreased and overnight wear repeated with the new lens. By following a bracketing process, the lens fit is gradually refined until a bull's eye pattern is achieved, at which point further alteration can be made to the refractive target if required, and the final lens ordered for dispensing.

LENS DELIVERY

As for all other lens-wearing modalities techniques for lens insertion, removal and care need to be demonstrated before the patient takes the lenses, ideally accompanied by printed explanatory documents (Cho et al., 2008). Lens insertion is the same as for standard RGPs (see Chapter 15), with the same instruction needed on how to recentre a decentred lens. Many practitioners also recommend instilling a viscous lubricating drop onto the back surface of the lens before insertion, making sure to avoid any trapped air bubbles in the solution. Removal techniques are also the same as for standard corneal RGPs, except that the patient needs to ensure that the lens is fully mobile and not bound before attempting removal. A simple way to ensure lens mobility is to have the patient instill a liquid lubricant drop and nudge the inferior lens edge several times by pushing up on the lower eyelid. The lens can then be removed following the standard method.

Any of the available RGP cleaning and conditioning solution combinations can be used for OK lenses. Due to the overnight-wearing modality, particular emphasis needs to be given to advice on avoiding tap water to reduce risk of Acanthamoeba infection, and lens cases should be replaced frequently to reduce microbial contamination (Wu et al., 2010a). On lens insertion the case should be cleaned by rinsing out with fresh conditioning solution, left open to air dry and face down on a clean towel or tissue (Wu et al., 2010b) during lens wear periods. The reverse-geometry design of OK lenses creates areas that can be difficult to clean using normal rub and rinse methods and are prone to deposit

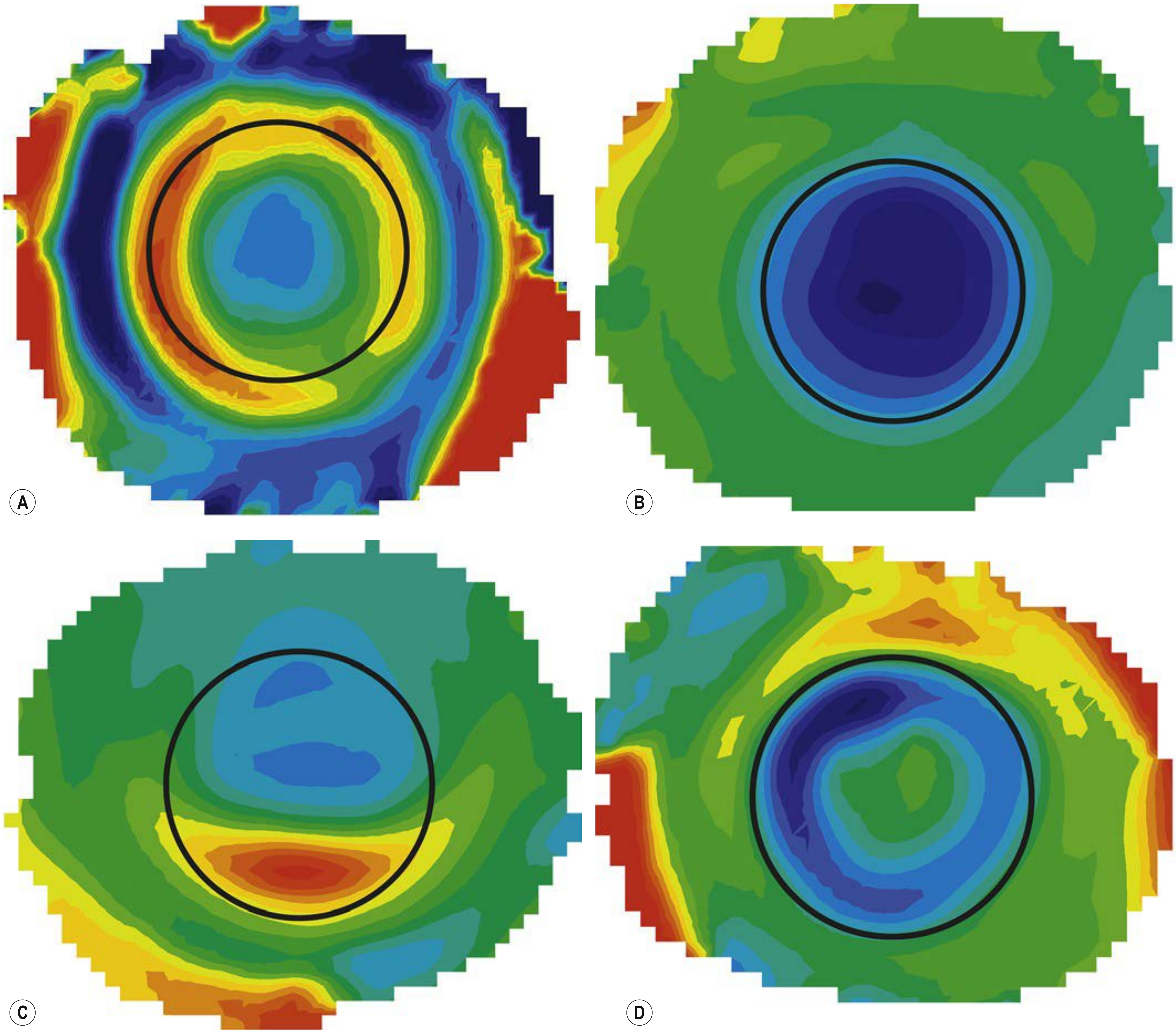

Fig. 32.4 Post-overnight wear corneal topography difference maps of an ideal 'bull's eye' displayed in tangential (A) and axial (B) format; flat fitting axial format 'smiley face' (C); and tight fitting axial format 'central island' (D). Red areas indicate corneal steepening, blue areas corneal flattening and green areas no change.

build-up that can interfere with the OK effect. Regular use of a deposit removal solution, such as Menicon Progent, can help to prevent this problem from occurring.

Aftercare

As is the case for all contact lenses, routine and comprehensive aftercare examination is essential. In the case of OK there are obvious differences in wearing patterns compared with daily-wear rigid contact lenses; however, no additional skills are required other than proficiency in corneal topography assessment.

VISIT SCHEDULE

Because changes to corneal curvature are induced to provide vision correction the aftercare visit schedule is typically more frequent than for daily-wear RGPs. Once a lens has been dispensed the patient needs to be followed closely to verify stability of refractive effect. Typically these visits should occur at increasing intervals starting at 1 week, then 1, 3 and 6 months after lens dispensing. Aftercare visits at 6-monthly intervals thereafter has been recommended by Cho et al. (2008). Visits should be scheduled as early as possible in the morning so that the maximum effect from overnight wear can be observed; however, it is useful to have at least one visit from later in the day to assess daytime regression of effect.

ASSESSMENT OF LENS FIT

Lens fit is assessed through observation of changes to corneal topography rather than direct observation of the lens on-eye. In fact, once a successful lens fit is established there is little to gain from assessing the lens on-eye. Corneal topography needs to be captured and a difference map created against the original baseline map. Fit is gauged by visual interpretation in the same manner as described for lens fitting. It is also useful to compare difference maps created at earlier visits to assess for any changes in OK effect over time (Nichols et al., 2000).

REFRACTION

Unless it is later in the day, or after a break from lens wear, where regression of effect becomes sufficient to cause some undercorrection, patients will attend with fully corrected vision. The correct balance of refractive change will vary across different patients depending on how responsive they are to OK and how quickly the effect regresses during the day. As already discussed, caution needs to be given to autorefractor results, which tend to overestimate refractive error after OK owing to sampling areas outside of the central treatment zone.

In most cases, a mild overcorrection of 0.50 to 0.75 D is expected at lens removal, which offers a cushion to absorb daytime regression; however, in some patients regression is less of an issue, allowing an alternative-night-wearing schedule to be adopted, or even greater periods between lens wear. In general, as long as fit is ideal, an increase or decrease in refractive effect is achieved by respectively flattening or decreasing the base curve of the lens.

OCULAR HEALTH

Anterior eye health needs to be assessed and monitored as usual for RGP lens wear, but with particular attention to factors pertinent to overnight lens wear. Myopic OK lenses are designed to create a flat-fitting optic zone, which makes them prone to binding during overnight wear. This can lead to mild central corneal abrasion detected by sodium fluorescein staining, and in some cases sufficient to cause epithelial erosion, particularly if a rubber contact lens remover is used. These problems can usually be resolved by instilling an ocular lubricant on waking and gently nudging the lens inferior edge with finger pressure on the eyelids.

Myopia Control with OK

Since the early use of rigid contact lenses, there have been attempts not only to correct myopia optically but also to inhibit the progression of myopia in children. Evidence for this effect has been controversial. More recently, the efficacy of overnight OK lens wear in inhibiting myopia progression in children has been postulated.

WHAT THE RESEARCH SHOWS

Cho et al. (2005) were the first to present evidence that overnight use of OK lenses in children not only temporarily corrects myopia but also restricts axial length elongation compared with an historical spectacle-wearing control group. They acknowledged that their study suffered from similar drawbacks to early OK studies, such as absence of appropriate control patients. Walline et al. (2009), using a similar study design, instead compared children wearing OK lenses with an historical soft-contact-lens-wearing group to find similar outcomes.

Studies using more robust protocols and stronger controls have since been published. Kakita et al. (2011) compared 42 children wearing OK lenses with 50 children wearing spectacles followed over a 2-year period. Axial length and myopia increased in both groups, with 36% less of an increase in OK compared with the spectacle wearers. A similar study design, which was randomized and single masked with spectacle-wearing controls, was completed by Cho and Cheung (2011) to report a 42% reduction in axial elongation over 2 years. Santodomingo et al. (2012) found 32% less axial elongation over 2 years, and Hiraoka et al. (2012) determined a 30% control effect over 5 years. Charm and Cho (2013) corrected 4 D of myopia with OK in children with −5.75 D or more spherical equivalent refraction, with single-vision spectacles correcting residual refractive error. In comparison with single-vision spectacle-wearing controls, the partial-OK treatment group showed a 63% reduction in axial elongation over 2 years. A cross-over study performed for a total of 1 year compared RGP daily wear in one eye with OK overnight wear in the other eye of paediatric subjects, and reported no axial growth in OK-wearing eyes over each 6-month study period. (Swarbrick et al., 2015).

The overall consensus from the research is that OK slows progression of myopia to a certain extent; however, the variability in reported outcomes suggests that there are discrepancies in response between individual subject cohorts. Indeed, in their cross-over study, which reported significantly less axial elongation in OK-wearing compared with RGP-lens-wearing eyes in both 6-month phases of the study, Swarbrick et al. (2015) reported that some individual subjects showed no axial length growth, whereas others showed strong axial growth with OK lens wear.

MECHANISMS FOR OK CONTROLLING MYOPIA PROGRESSION

When considering possible mechanisms for a myopia-controlling effect, separate studies have shown that myopic OK induces a positive shift to the spherical aberration of the eye (Joslin et al., 2003; Hiraoka et al., 2005; Gifford et al., 2013) and alters the shape of the image shell that is formed at the retina (Kang and Swarbrick, 2011).

Studies in chicks and primates have shown that the shape of the retinal image shell is influential in axial elongation, with hyperopic defocus (image focus posterior to the retina) causing increase in axial length, and myopic defocus (image focused anterior to the retina) inhibiting axial eye growth (Fig. 32.5). Charman et al. (2006) were the first to report that OK induces a myopic shift in peripheral refraction relative to macular focus. By fitting children with OK lenses in one eye and traditional rigid gas-permeable lenses (RGP) in the fellow eye over 3 months, Kang and Swarbrick (2011) confirmed the finding of relative peripheral myopic defocus in OK-lens-wearing eyes. The fellow RGP-lens-wearing eyes showed no change to peripheral refraction and exhibited peripheral hyperopic defocus as was shown at baseline prior to lens wear. It appears that OK provides the same peripheral image formation that has been shown to inhibit eye growth in animal models, while ‘standard’ contact lenses instead leave the eye in a less-favourable state of peripheral hyperopic defocus.

It has also been speculated that OK-induced changes to spherical aberration could be responsible for the myopia-controlling effect. Tarrant et al. (2009) reported an increase

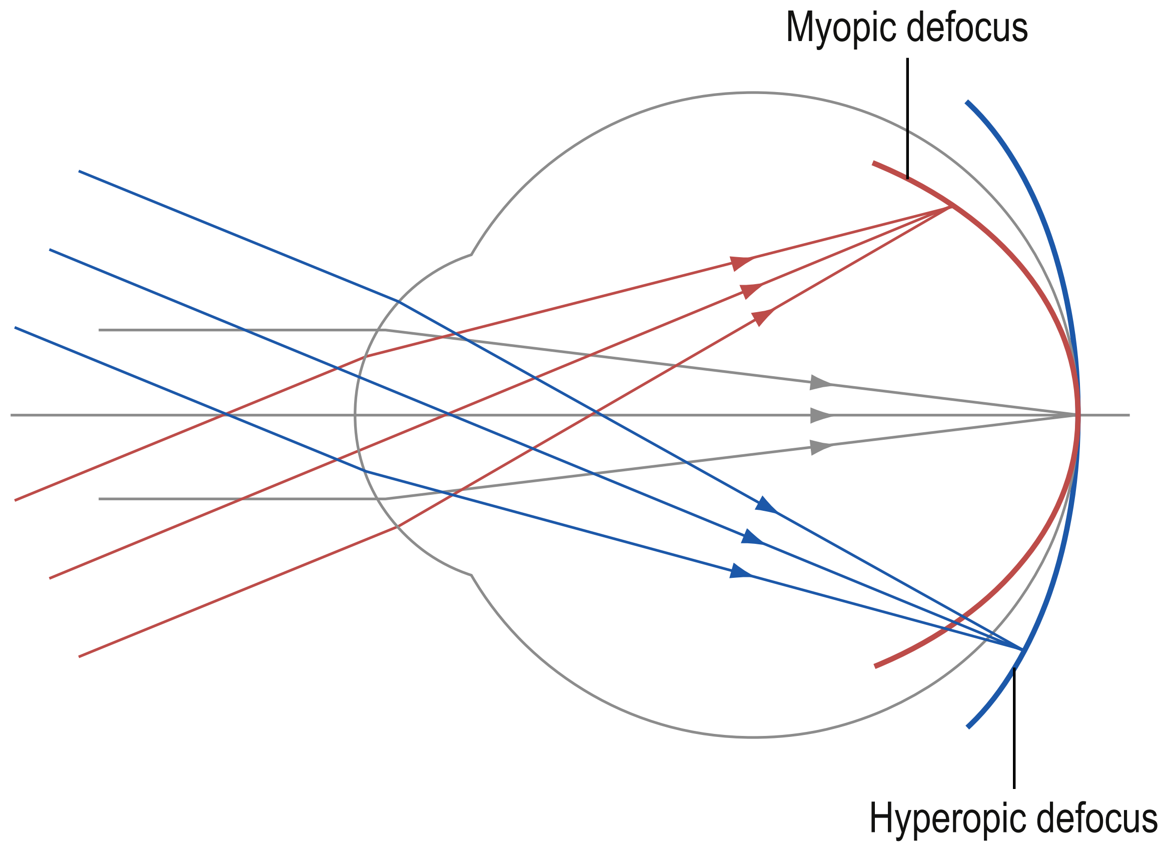

Fig. 32.5 Model of relative hyperopic and myopic peripheral refraction image profles.

in positive spherical aberration from OK and coincidentally found improvement in image quality, measured as point spread function, at a range of near-accommodative targets. Although they did not measure accommodative lag directly, the authors speculated that their results were consistent with OK-induced changes to spherical aberration resulting in a reduction to accommodative lag, which would have the effect of shifting the whole retinal image shell in a favourable myopic direction. Gifford et al. (2013) simultaneously captured corneal and ocular aberrations after myopic OK lens wear to find increases to positive spherical aberration in both measurements; however, over time there was less change to ocular compared with corneal spherical aberration over time. The authors suggested that the same accommodative response reported by Tarrant et al. (2009) could explain the difference in effect.

As much as the mechanism for a myopia-controlling effect is not fully known, the longevity of effect also remains to be fully understood. In a recent study, Swarbrick et al. (2015) fitted children with daily wear RGP lenses for 6 months wear in one eye during the day, and overnight OK lenses in the fellow eye. They then discontinued wear for 2 weeks to regress the OK effect and then wear was continued except that the lens-wearing pattern was swapped between eyes. Increases in axial eye length with the eyes wearing RGP lenses were reported, while the fellow eyes wearing OK showed no increase. When the lens types were swapped after 6 months the effect was found to follow the lens. However, the authors found that there was an apparent acceleration in eye growth rebound effect after the OK-lens-wearing eyes were swapped at the 6-month period to wearing RGP lenses.

The apparent rebound effect reported by Swarbrick et al. (2015) led the authors to suggest that 6 months OK wear is insufficient for stable myopia control, but raises the question on the necessary required period of OK wear to achieve stabilization and avoid rebound effects. Similarly the question on how long OK is effective at slowing progression of myopia is poorly understood, although there is some information available on the subject. Johnson (2010), using cumulative clinical data for 62 paediatric OK wearers of at least 18 months duration, demonstrated that progression in myopic refraction became clinically relevant (change of −0.25 D) only after 42 months of OK lens wear. Hiraoka et al. (2012) found that the annual increases in axial length were significantly different between the OK-lens and spectacle-wearing control groups for the first, second and third years but not the fourth or fifth years of wear.

Whatever the mechanism, research provides compelling evidence that OK is influential in slowing progression of myopia; however, further research is needed to elucidate the exact mechanisms and also whether OK lens designs can be altered to better enhance the myopia controlling effect they have been shown to provide. Further information on myopia control and alternative mechanisms for providing a myopia control effect are covered in Chapter 33.

Conclusion

OK has come a long way in recent years, and is gaining increased global popularity, particularly as a clinical modality to slow progression of myopia. Due to its reliance on measurement of corneal topography, OK still remains a niche modality practised mainly by practitioners who fit specialty contact lenses. However, evidenced through increased attendance at OK conferences around the world, and interest in the clinical press, it is clear that an increasing number of practitioners are becoming involved with OK. The reason for this increased interest in practitioners and patients alike is not hard to elucidate, given that OK is one of the only forms of refractive correction that has been shown to slow progression of myopia significantly. How this develops into the future remains to be seen, but for now there is a considerable body of knowledge to support OK as a safe technique to adopt in contact lens practice.

Many studies have shown that OK is effective in modifying refractive error. The treatment effect, however, is transient and requires continued overnight wear to maintain, though some patients manage to regularly skip a night or two of wear and still maintain an acceptable level of refractive correction. When correctly fitted, modern reverse-geometry lenses are reliable in correcting up to around −4.50 D of myopia with no more than 1.50 D of with-the-rule corneal toricity. Improvements to lens designs have simplified lens fitting to help overcome the problems of predictability that were reported in earlier studies. Some manufacturers report success in correcting higher degrees of myopia and astigmatism; however, there is currently no scientific evidence to support these claims, so patients should be cautioned that outcomes are less reliable when attempting higher corrections. The same applies to OK correction of hyperopia and presbyopia, which, although proven as possible, have been shown to be reliable only in correcting low refractive errors.

When considering safety, in general, wearing OK lenses brings similar risks as wearing any other form of contact lenses. However, in common with all forms of contact lenses, overnight wear brings with it the increased risk of keratitis (Morgan et al., 2005; Watt and Swarbrick, 2007). It is possible that the OK-induced changes to corneal epithelial profile and corneal nerve fibres could further increase the risk of complications from overnight lens wear; however, the current limited clinical evidence suggests that this is not the case. It is apparent from many of the reported cases of MK in OK that the lenses coming into contact with tap water is a high-risk factor for infection. As with all forms of contact lens wear, good hygiene and regular aftercare are paramount in ensuring safe wear of OK lenses; but also, in particular with OK, patients should be constantly reminded to avoid tap water contamination so as to ensure safe OK lens wear.

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Access the complete references list online at http://www.expertconsult.com.

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33

Myopia Control

PADMAJA SANKARIDURG | BRIEN A HOLDEN

Introduction

Recent years have seen an surge in interest for solutions to control the progression of myopia fuelled by evidence indicating (a) a rising prevalence of myopia all over the world and especially many East Asian countries, which have a prevalence of 70% or over in 17-year-old teenagers (Lee et al., 2015; Wu et al., 2015) and (b) a concurrent increase in the number of high myopes (≥−5.00 D). High myopia is associated with the risk of sight-threatening complications such as myopic macular degeneration, retinal detachment and glaucoma (Vitale et al., 2009; Chen et al., 2012; Sun et al., 2012; Le et al., 2013; Koh et al., 2014; You et al., 2014). Myopic macular degeneration has been identified to be a major cause of blindness in studies from Japan and Taiwan (Hsu et al., 2004; Iwase et al., 2006). With an estimated 1.5 billion people considered to be affected, myopia is the most important cause of distance visual impairment and is associated with significant health and socioeconomic burden.

A model projecting future prevalence rates for myopia, high myopia and myopic retinopathy based on current prevalence rates has suggested that myopic retinopathy is likely to be a leading cause of vision loss by 2050 (Holden et al., 2016). Clearly, it is desirable to reduce: (a) the number of eyes reaching high levels of myopia to prevent or decrease the risk of myopia-related sight-threatening complications, (b) the burden associated with progressing myopia (e.g. less frequent change of optical devices) and (c) vision impairment due to uncorrected myopia. Currently, myopia management mostly involves correction with spectacles and contact lenses and to a lesser extent with refractive surgery and orthokeratology. These approaches correct for the refractive error and eliminate blurred vision at distance but, with the exception of orthokeratology and possibly refractive surgery, do not arrest or slow the axial length increase that leads to progression.

Is it possible to stem the rising burden by controlling or slowing eye growth? Myopia is believed to be a complex condition with both genetic and environmental factors playing a role in its onset and progression. Although the role of the many factors and their interactions are not fully understood, fortunately research evidence has been accumulating, indicating that it is well within the reach of the practitioner to slow the progress of myopia.

In this regard, there is compelling evidence from animal studies to demonstrate that environmental factors such as form deprivation and optical defocus can be used to manipulate predictably the development and progression of refractive errors. In late 1970s, Wiesel and Raviola sutured the lids of monkeys to induce form deprivation and showed that it results in axial elongation and consequently myopia (Wiesel and Raviola, 1977). Later experiments that blocked/restricted light to certain fields of the eye and varied ambient illumination showed that myopia could be induced in experimental animal models (Wallman et al., 1987). Also, significantly, experiments demonstrated that optical defocus (plus and minus lenses creating myopic and hyperopic defocus) could be used to alter eye growth in a highly regulated manner involving both direction and magnitude (Diether and Schaeffel, 1997; Schaeffel et al., 1988; Smith et al., 2013).

In addition, over the years there have been a number of anecdotal reports, strategies and interventions trialled in humans with various optical and pharmaceutical approaches that show that it is feasible to slow the progress of myopia. For example, a number of spectacle interventions involving bifocal and multifocal spectacle lenses provide evidence that it is feasible to control its progression (Gwiazda, 2009; Cheng et al., 2014; Leung and Brown, 1999).

Contact lenses clearly have a role to play. As early as the 1970s, it was suggested that rigid contact lenses could play a role in slowing the progression of myopia by either processes related to corneal flattening or other unknown mechanisms. More recently, a number of novel contact lens designs were assessed in clinical trials for their efficacy in slowing the progression of myopia and found to have varying levels of success. Overnight orthokeratology, used to eliminate myopia temporarily, was also found to slow the progress of myopia (Cheung et al., 2004). This chapter reviews the various contact lens approaches that have been trialled to date and also discusses a fitting and management strategy. Methods of myopia control by fitting and reshaping the cornea with orthokeratology lenses are presented in detail in Chapter 32.

Patient Selection and Risk Factors

There is no clear information on when myopia ceases to progress. Some studies report that myopia stabilizes in the late teens, but there is also information indicating that, in certain eyes, myopia continues to progress, albeit slowly, even after the teenage years and even in young adults from their twenties and well into their thirties (Lv and Zhang, 2013). In addition, there exist data showing that onset of myopia can also occur in the early to late twenties, especially during the university years (Kinge and Midelfart, 1999).

Thus, provided that there is no contraindication to contact lens wear, and the lens provides good, or acceptable, vision at all distances, any individual with myopia is a candidate for a myopia control contact lens. However, some myopes (e.g. young children) show greater progression compared with others and therefore it is essential to understand and identify the 'at-risk' group for faster progression to ensure better outcomes.

Evidence indicates that the younger the onset of myopia, the greater is the risk of progression of myopia (Donovan et al., 2012; Sankaridurg and Holden, 2014). Fig. 33.1 provides an estimated progression model for spherical equivalent (SE) refractive error for Asian children with myopia derived from 633

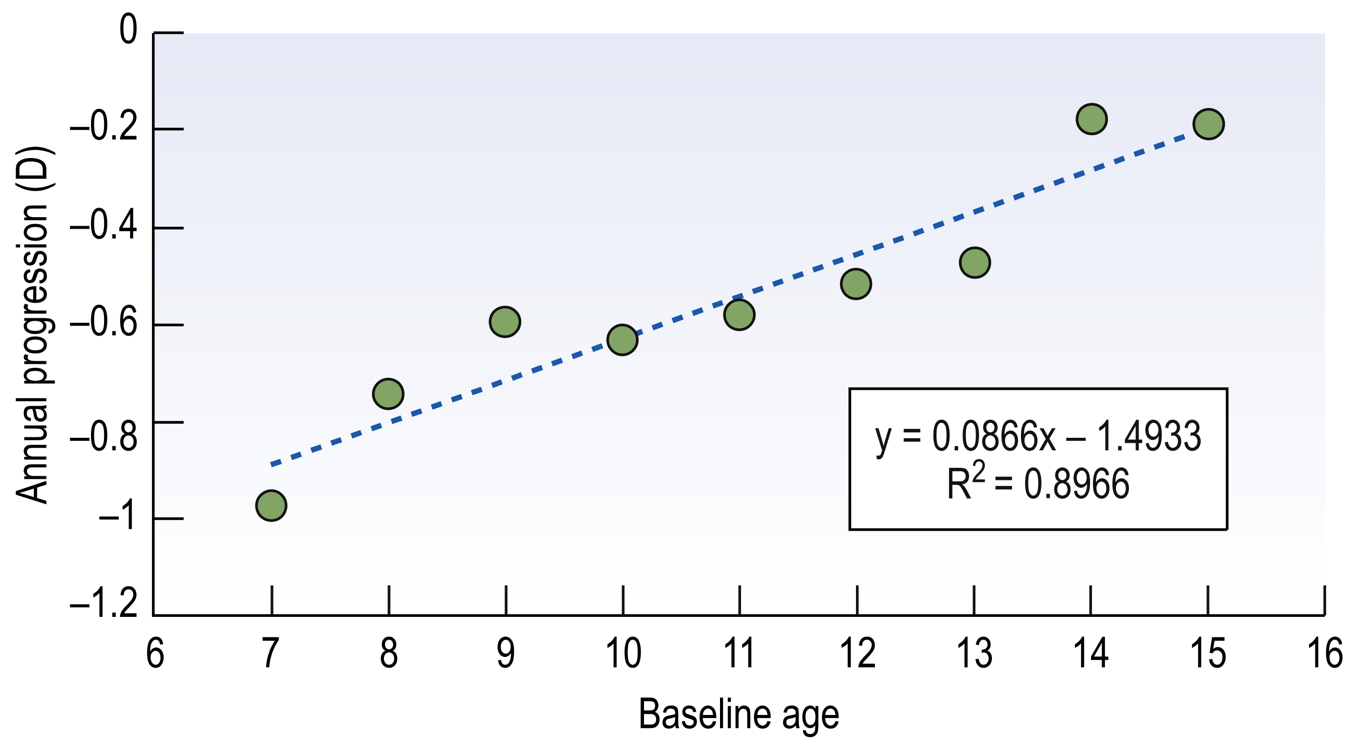


Fig. 33.1 Progression model for spherical equivalent refractive error for Asian children with myopia.

children aged 7–15 years and wearing single-vision spectacles. These data indicate that younger children have a higher rate of progression compared with older children, with progression decreasing with each passing year. Thus a child with onset of myopia at 7 or 8 years may reach higher levels of myopia much earlier than a child with onset of myopia at 12 years. To limit the rise in prevalence of high myopia, (i.e. myopia of −5.00 D or more), one needs to consider managing children with myopia, especially those that are less than 9 years of age, with an appropriate myopia control strategy.

Other than age, ethnicity and parental myopia have also been found to increase the risk of progression of myopia. Children of Asian descent show a greater shift towards a more myopic spherical equivalent refractive error compared with predominantly European or Caucasian children (Donovan et al., 2012; French et al., 2013a, b). For a child with myopia with an estimated mean age of 9.3 years, the predicted annual progression was −0.82 D / year for children of Asian descent and −0.55 D / year for children of European descent (Donovan et al., 2012).

In a group of non-myopic children, grouped by parental history of myopia, those with two parents who were myopic showed a more myopic shift in refraction over 1 year compared with those with only one myopic parent or no myopic parents (Lam et al., 2008). Other studies have also found that parental myopia was a significant risk factor, with adjusted analyses showing myopic children with two myopic parents progressing faster compared with those with only one myopic parent or those with no parental myopia (Kurtz et al., 2007; Loh et al., 2015). Although parental myopia is generally considered to be a risk factor for both development and progression of myopia, its role in progression is not clear, with the few studies failing to demonstrate an effect of parental myopia on development and progression (Edwards, 1998; Yang et al., 2009).

In addition to the above-mentioned risk factors, gender, outdoor / indoor time and peripheral refractive errors are also considered to have a role in the progression of myopia.

A number of studies have reported the prevalence of myopia to be higher in females than in males (You et al., 2012; Wu et al., 2013) but others failed to find such an association (Chen et al., 2013; Guo et al., 2013). Faster progression was also reported in females (Liao et al., 2014). Based on a meta-analysis of progression data from spectacle wearers, Donovan et al. (2012) reported that, for a baseline age of 8.8 years, estimated annual progression was −0.80 D / year for females and −0.71 D / year for males (Donovan et al., 2012). The reasons for this higher progression rate in females are not understood, but it is suggested that girls may have a more myopiagenic activity pattern (increased near work and less outdoor time) compared with boys (French et al., 2013a).

Indoor / outdoor time is seen to be associated with both onset and progression of myopia. Factors such as being indoors, excessive near work and not looking at distant targets have long been held to be myopiagenic. Also, groups such as young school age children, university graduates, occupations requiring close- and near-work activities such as microscopy are considered to be at higher risk of progression (McBrien and Adams, 1997; Ting et al., 2004). Whereas some studies found protective associations for time outdoors reducing the risk of myopia, others have not found such an association (Rose et al., 2008; Jones-Jordan et al., 2012). However, a prospective, randomized clinical trial found that 80 minutes of outdoor time during school recess each day for a year reduced the incidence of new myopia by nearly 50% and also slowed the progress of myopia (Wu et al., 2013).

Defocus at the peripheral retina is said to contribute to progression with those with hyperopic defocus at the periphery at greater risk (Hoogerheide et al., 1971; Mutti et al., 2007). Relative peripheral hyperopia is commonly found in myopic eyes (Atchison et al., 2006; Lin et al., 2010) and is possibly or weakly linked to progression (Kang et al., 2012; Radhakrishnan et al., 2013) or with less central myopia progression (Berntsen et al., 2013). In addition to the above factors, it has been suggested that near phorias, especially esophoria (Goss and Rainey, 1999; Gwiazda et al., 2004), esofixation disparity, high accommodative convergence / accommodation (AC / A) ratio (Price et al., 2013) and lag of accommodation (Gwiazda et al., 2004; Price et al., 2013) have a role to play, but other studies have not found any correlation between lag and progression (Mutti et al., 2006; Weizhong et al., 2008; Berntsen et al., 2011).

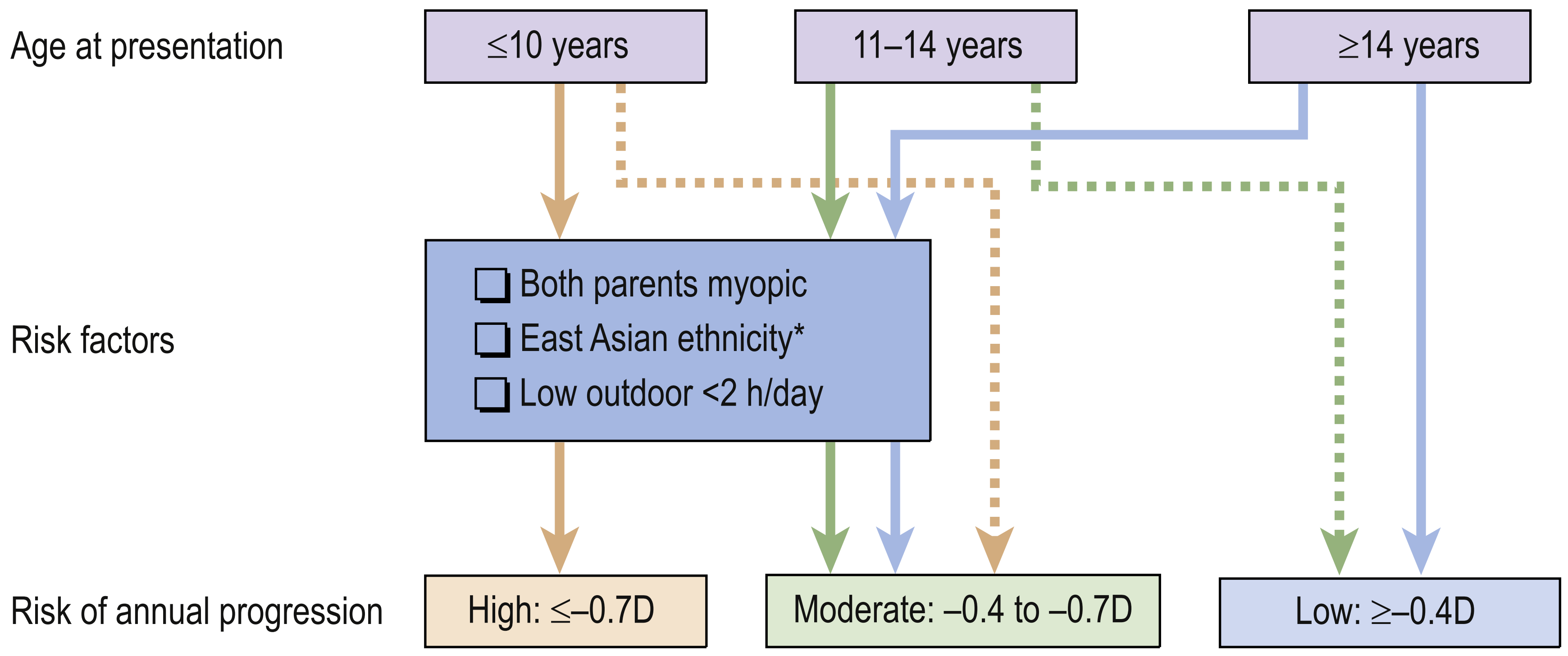
Fig. 33.2 depicts the Brien Holden Vision Institute (BHVI) scorecard based on the well-established risk factors of age, parental myopia and outdoor time for evaluating the risk of progression. The scorecard provides a guideline for the practitioner to categorize individuals based on the risk profile so that management with a suitable approach and follow-up visits can be tailored to the individual.

Types of Contact Lenses

Over the years, a number of optical strategies using contact lenses have been assessed for their efficacy in controlling the progression of myopia. This section reviews the various strategies and the results. A summary is presented in Table 33.1.

SINGLE-VISION RIGID LENSES

Clinical studies from the 1990s reported that daytime lens wear with single-vision rigid contact lenses (as opposed to orthokeratology lenses, which are discussed in Chapter 32) showed less progression compared with matched spectacle lens wearers. Some corneal flattening was found with rigid lens wearers, but the authors concluded that the refractive power change attributed to corneal flattening could not fully explain the significant difference in progression between the rigid lens wearers and the spectacle lens wearers (Grosvenor et al., 1991). However, this finding was not supported by evidence from randomized clinical trials. In a study involving 564 children randomized to either rigid lenses or spectacles, at the end of 24 months there was no difference in the progression of myopia in those wearing



** Includes East Asia and Singapore*

Fig. 33.2 The Brien Holden Vision Institute (BHVI) scorecard for evaluating risk of annual progression of myopia.

TABLE 33.1 Summary of Evidence for Myopia Control with Contact Lenses

Lens Type	Authors	Control Group	Percent Reduction vs Control	Duration of Study (years)	Significant Difference Between Groups	Difference in Dioptric Value (D)	Evidence for Myopia Control
Rigid contact lens	Katz et al. (2003)	Spectacle	−4	2	No	0.05	No evidence for myopia control.
	Walline et al. (2004)	Soft contact lens	29	3	Yes	0.63 unadjusted	Some change but not substantiated by axial growth patterns
Soft contact lens	Horner et al. (1999)	Spectacle	−18	3	No	0.18	No evidence for myopia control.
	Walline et al. (2008)	Spectacle	−17	3	No	0.22 adjusted, 0.19 unadjusted	Progression may be influenced by material, mode of lens wear and lens power profile
Bifocal contact lenses	Walline et al. (2013)	Soft contact lens	50	2	Yes	0.50 adjusted	Slow progress of myopia.
	Aller & Wildsoet (2006)	Soft contact lens	72	1	Yes	0.56 unadjusted	
Peripheral defocus management	Holden et al. (2012)	Soft contact lens	39	43 months	Yes	0.64 unadjusted	Slow progress of myopia
	Sankaridurg et al. (2011)	Spectacle	34	1	Yes	0.29 adjusted	
Simultaneous Dual focus	Lam et al. (2014)	Soft contact lens	25	2	Yes	0.20 unadjusted	Slow progress of myopia
	Anstice & Phillips (2011)	Soft contact lens	37	10 months	Yes	0.25	

rigid lenses compared with those wearing spectacles (Katz et al., 2003). In a later 3-year trial where children were randomized to either rigid or soft lenses, there was a significant difference in the rate of progression, with rigid lenses having a slower rate (spherical equivalent −1.56 ± 0.95 D) versus −2.19 ± 0.89 D with soft lenses (Walline et al., 2004). However, the reduction in rate of change in myopia was not reflected in the axial length change between the groups. It was indicated that in part this may have been due to the corneal flattening that occurred with the rigid lenses.

SINGLE-VISION SOFT LENSES

Data from prospective, clinical trials do not show a difference in the rate of progression of myopia with single-vision soft contact lenses compared with spectacles. In one randomized trial conducted for 3 years, in adolescents aged 11–14, no significant difference was found in the spherical equivalent change in myopia between spectacle lens wear versus contact lens wear (Horner et al., 1999). Similarly, a later large-scale, randomized clinical trial involving children aged 8–11 years with myopia randomized to either spectacles or soft contact lenses (1-Day Acuvue or Acuvue 2, Vistakon, Jacksonville, Florida) found no significant difference in the rate of progression of myopia between the two groups. The adjusted difference between the groups was −0.22 D, with slightly higher progression for contact lens wearers (Walline et al., 2008). However, while the above-mentioned studies do not show that soft contact lenses influence myopia progression, their role cannot be conclusively ruled out as factors such as lens material, fit and power profile have been indicated or have been found to influence myopia.

Lens Material and Oxygen Transmissibility

Studies comparing low Dk/t and high Dk/t lenses on an extended-wear basis have consistently observed an increase in myopia in eyes wearing low Dk/t lenses and this was attributed to the hypoxic state, with the low Dk/t lenses leading to corneal hypoxia and swelling, which resulted in an increase in myopia (Dumbleton et al., 1999; Blacker et al., 2009; Jalbert et al., 2004). In a 9-month study, eyes in the extended-wear low Dk/t group demonstrated an increase in myopia of −0.30 D in 9 months, compared with no change in the eyes wearing silicone hydrogels for up to 30 nights (Dumbleton et al., 1999). The phenomenon was recognized with the term 'myopic creep'. No such phenomenon was observed during daily wear of lenses.

Lens Profile

More recently, it was observed that the power profiles across the optic zones of commercially available soft contact lenses vary greatly (Wagner et al., 2015). Many lenses showed an increasing minus power or negative spherical aberration towards the periphery of the optical zone. The power distribution or the lens profile is said to affect the peripheral refraction and possibly the growth of the eye (Shen et al., 2010; Kwok et al., 2012).

Practitioners need to be aware of the potential influence of lens material, mode of lens wear and the optical profile of the lens on myopia progression and make an informed decision on a lens type that they deem is suitable for a given eye.

BIFOCAL/MULTIFOCAL LENSES

Data from case reports, cross-over studies and comparative group longitudinal studies support the use of bifocal/multifocal contact lenses to slow the progression of myopia. The lens that features commonly is a centre-distance, concentric design, simultaneous vision bifocal with an add power of +1.50 D to +2.00 D. A number of mechanisms have been proposed to explain the myopia control effect of bifocals and they include: (a) bifocals serve to correct the accommodative lag, which is considered to be a stimulus for eye elongation; (b) bifocals serve to alter the peripheral retinal image forwards, as peripheral retinal hyperopia is considered a risk factor for progression; and (c) bifocals impose sustained myopic defocus across the retina, which is considered to be inhibitory for eye growth.

In a case study (Aller and Wildsoet, 2008) of 12-year-old identical twins with myopia, each of the twins were randomly fitted with single-vision contact lenses or bifocal contact lenses and followed for 2 years. At approximately 13 months, the twin fitted with the bifocal contact lens showed a 0.13 D reduction in myopia, compared with an increase in myopia of 1.19 D in the twin fitted with single-vision contact lenses. In the second year, the twin fitted with the bifocal contact lens showed progression of −0.28 D. The twin with the single-vision contact lens was switched to a bifocal contact lens and then showed a reduction in myopia of 0.44 D. The bifocal lens was said to be a multizone simultaneous vision design and specifically a distance centre with alternating near and distance zones and an add power of +2.00 D.

Howell (2008) reported on a series of children who were initially fitted with multifocal spectacle lenses in year 1 and then switched to a centre-distance multifocal lens design of +1.50 D add in year 2. The rate of progression with the multifocal contact lenses was said to be slowed by nearly 68% (−0.56 ± 0.17 D in year 1, versus −0.18 ± 0.23 D in year 2). Although promising, it is not clear whether the result was adjusted for progression with age.

More recently, myopic eyes fitted with a centre-distance bifocal contact lens showed 50% less progression for spherical equivalent refractive error (−1.03 ± 0.06 D for single-vision contact lens wearers and −0.51 ± 0.06 for the soft multifocal lens wearers) and a 29% reduction in axial length during a 2-year treatment period, compared with a group fitted with single-vision contact lenses. The bifocal lens was a centre-distance bifocal contact lens (Proclear Multifocal, CooperVision, Fairport, NY) with an add power of +2.00 D. The authors concluded that the treatment effect, the effect seen with these lenses, supported the results reported with bifocal contact lenses, simultaneous dual-focus lenses and lenses designed to control peripheral hyperopia (Walline et al., 2013). In yet another randomized clinical trial, 86 myopic children aged 8–18 years were randomized to wear either an Acuvue single-vision or an Acuvue bifocal contact lens (Vistakon, Jacksonsville, FL); after a year of lens wear, there was a 72% reduction in cycloplegic spherical equivalent (−0.78 ± 0.45D with single vision and −0.22 ± 0.34D with bifocals) and a 79% reduction in axial length (Aller and Wilssoet, 2006). The study utilized four different add powers selected for each individual based on their associated esophoria at near (Personal communication, Dr Thomas Aller, CA).

SIMULTANEOUS DEFOCUS OR DUAL-FOCUS LENSES

As stated in the previous section, a lens that induces simultaneous myopic defocus across parts of the retina whilst maintaining a simultaneous clear image to maintain good vision is said to slow the progress of myopia (Anstice and Phillips, 2011). In marmosets, imposing negative (hyperopic) and positive (myopic) defocus using concentric contact lenses resulted in less eye growth in eyes with such multizone lenses compared with eyes wearing single-vision control lenses (Benavente-Perez et al., 2012).

In a 20-month, contralateral, cross-over clinical trial involving 40 children, eyes randomized to the dual-focus lens for the first 10 months showed a 37% decrease in progression of myopia with respect to spherical equivalent and axial length progression decreased by 49%. In the second 10 months, eyes that wore the dual-focus lenses showed less progression compared with the eyes wearing single-vision lenses (Anstice, 2009; Anstice and Phillips, 2011). In a more recent clinical trial, concentric alternating distance correcting and defocusing zones that were said to provide simultaneous myopic defocus at the retina were assessed in a randomized, double-masked study conducted for 2 years. Over the 2 years, the groups wearing the simultaneous defocus lenses showed 25% less progression of myopia for spherical equivalent (0.59 ± 0.49 D with defocus incorporated lenses and 0.79 ± 0.56 D for single-vision lenses) and 32% less progression in axial length compared with the group wearing single-vision lenses (Lam et al., 2014).

A commercially available contact lens, MiSight® (Coopervision, Pleasantville, CA), is available for myopia control. Publications relating to MiSight® refer to the dual-focus contact lens tested in the DIMENZ trial (Anstice, 2009) and therefore the lens design may have its origin in that dual-focus contact lens. The MiSight® lens is available in a limited number of countries as a daily disposable contact lens (see http://coopervision.com.my/contact-lenses/misight) and has a treatment zone power of +2.00 D that appears as concentric rings (Fig. 33.3) (Kollbaum et al., 2013).

LENSES THAT MANAGE PERIPHERAL HYPEROPIC RETINAL DEFOCUS

Contact lenses designed to reduce peripheral hyperopic defocus have been shown to slow the progress of myopia. Myopic eyes, both in an uncorrected state and when corrected with conventional optical approaches, demonstrate relative hyperopia at the periphery relative to centre (Atchison et al., 2006) and, in animal models, peripheral hyperopia was seen to lead to axial myopia (Smith et al., 2009).

Treatment contact lenses with a clear central zone and a relatively positive power in the periphery (+1.00 D at 2 mm semichord and +2.00 D at the edge of the treatment zone of 9 mm) aimed at reducing peripheral hyperopic defocus were assessed prospectively in a clinical trial involving children with myopia and compared with children wearing single-vision spectacle lenses. A schematic diagram is given in Fig. 33.4. At the end of 1 year, eyes wearing lenses that were designed to reduce defocus and / or create myopic defocus at the retinal periphery slowed progression of myopia by 34% for spherical equivalent refractive error (−0.86 D with spectacles versus −0.57 D for contact lenses) and 33% for axial length (Sankaridurg et al., 2011). In another study, children with myopia and aged 8–14 years were randomized to a test lens designed to reduce peripheral defocus (clear central zone to correct for distance and a relative positive power of +1.50 D in periphery) or a single-vision soft contact lens for 43 months. At the end of 43 months, progression was 39% less for spherical equivalent (−0.99 ± 0.58 D, with the test lens compared with 1.63 ± 0.66 D with the control group) and 41% less for axial elongation (Holden et al., 2012). Also, the leading hypothesis for the slowing in eye growth seen with orthokeratology lenses attributes the effect to correction of peripheral hyperopic defocus (Kang et al., 2013).

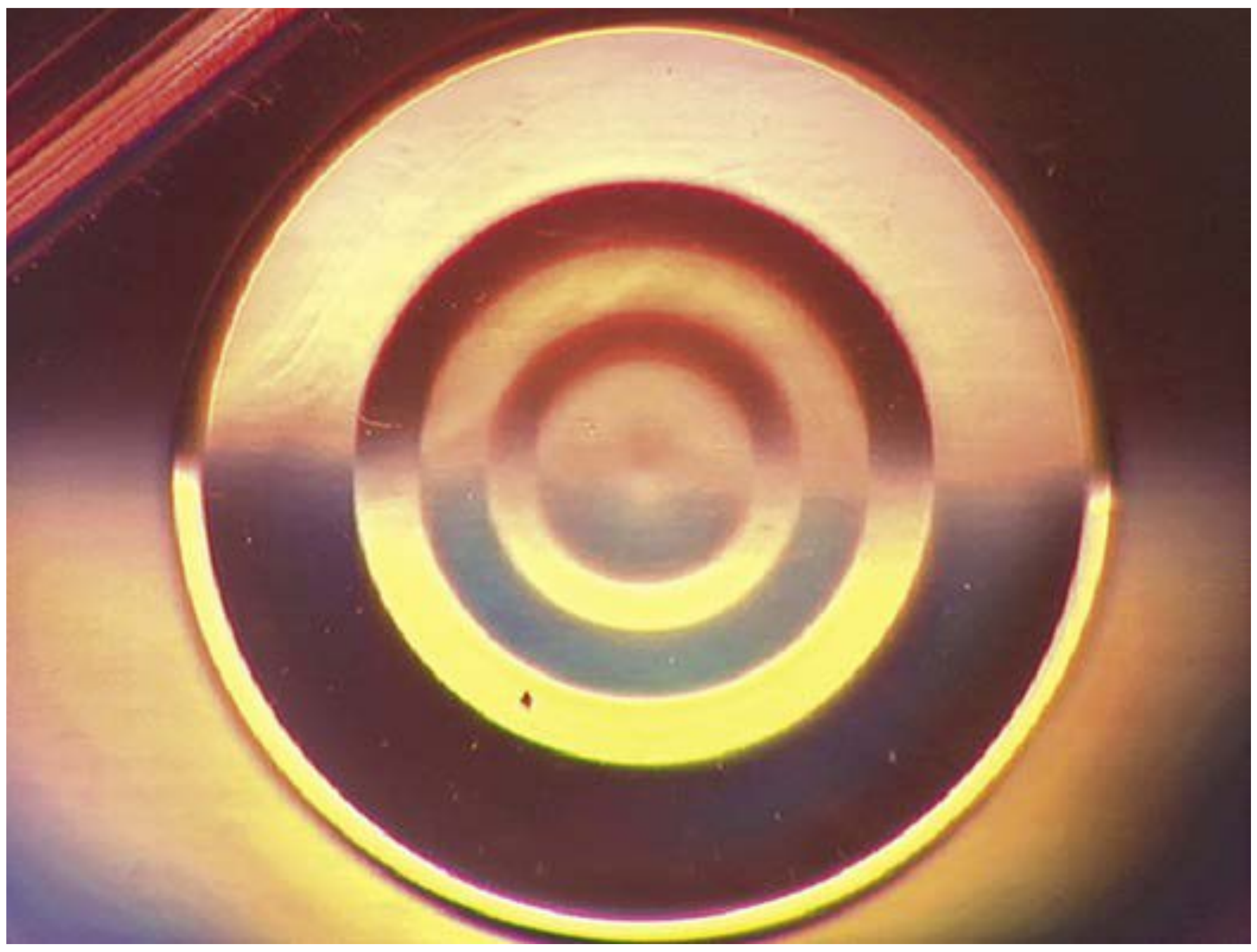


Fig. 33.3 Concentric rings visible on the MiSight® lens with the Ho optical quality analyser.

In addition to the above-mentioned lenses, there are a number of other technologies that are currently being assessed for their efficacy in slowing the progress of myopia with the use of contact lenses. Only preliminary and limited data are available at the present time and these are briefly described below.

LENSES WITH POSITIVE SPHERICAL ABERRATION

Contact lenses that incorporated two levels of positive spherical aberration were examined for their efficacy in slowing the progression of myopia compared with two control groups wearing spherical soft contact lenses or spectacle lenses in a randomized controlled trial involving 466 children with myopia. The study was conducted for 2 years and it was said that the effect of treatment in controlling axial elongation was greater in the lens with higher spherical aberration. Positive spherical aberration is said to have the potential to slow myopia progression by slowing the axial growth of the eye (Cheng and Brennan, 2013)

LENSES WITH AN EXTENDED DEPTH OF FOCUS

In an ongoing clinical trial involving children with myopia, specially designed soft contact lenses with an extended range of focus that corresponded to near, distance and far distances were able to slow the progression of myopia by nearly 50% at 6 months. Two lens designs are currently under investigation. The contact lenses are considered to slow the progress of myopia by (a) the slope of the retinal image quality degrading for points beyond the far focus and thus reducing the incentive for the eye to grow in that direction and (b) creating simultaneous myopic defocus across a large section of the retina (Bakaraju et al., 2015).

Fitting a Myope with Contact Lenses

It is without doubt that specially designed contact lenses can be used to control the progression of myopia. However, approaching a young myope, usually a young child, and their carer with the option of contact lens wear requires that the practitioner provides a clear list of the benefits that contact lens wear offers over commonly prescribed spectacles. Contact lens wear in children has been shown to improve quality of life (Walline et al., 2007a), with children and teens reporting improvement in their appearance and participation of activities. Also, young children have been shown to care and manage lens wear independently. More specifically, with respect to controlling the progression of myopia, trends indicate that contact lenses may be

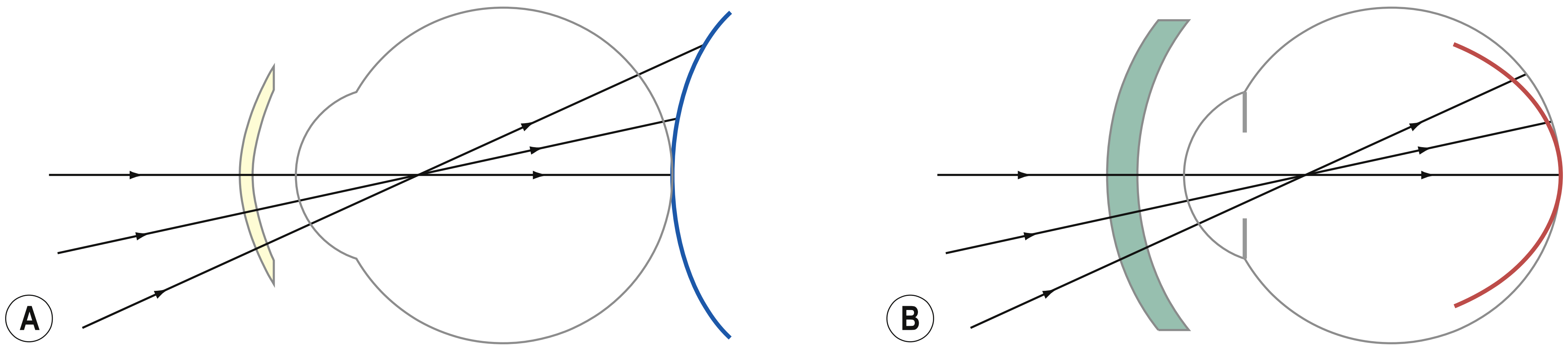


Fig. 33.4 Myopic eye corrected with (A) conventional lenses, and (B) lenses that correct peripheral retinal defocus.

able to deliver a better mean reduction in myopia progression in comparison with spectacle lenses. Table 33.2 summarizes studies that have demonstrated a mean reduction in progression of spherical equivalent seen with spectacles designed to control myopia. Unlike a spectacle lens, where the eye moves independently of the spectacle lens, contact lenses are aligned with the movements of the eye and are likely to deliver the stimulus effectively. Also, compliance with lenses such as progressive addition spectacles has been identified as a problem, for instance with children not looking through the specially designed near portion for near viewing.

MEASUREMENTS AND EXAMINATION

When considering fitting children and young adults with contact lenses, a cycloplegic refraction to determine the amount of refractive error accurately is recommended. There exists a number of studies showing that a non-cycloplegic refraction is inaccurate and unreliable, mostly due to the influence of accommodation, and may show a more than normal myopic refractive error (Fotedar et al., 2007; Hu et al., 2015) The errors that may occur could be twofold: (a) a non-myope could be erroneously classified as a myope and (b) a myope could be categorized as having higher amount of myopia than actually exists.

The external eye dimensions, especially the radius of curvature of the cornea, show minimal changes from the age of 7 years (Gordon and Donzis, 1985; Zadnik et al., 2003; Wong et al., 2010). Therefore, children as young as 6–7 years old can be fitted with contact lenses that are currently available on the market without the need for having specially designed lenses (Fig. 33.5). Also, modern contact lens technology has evolved to an extent that there is little need for keratometry or corneal topography measurements to help with the lens selection, with the exception of rigid lens fitting. However, where feasible it is advisable to take these measurements as they are useful in determining corneal toricity, and serve as a baseline record for evaluation of any future changes in corneal topography and also for differential diagnosis of conditions such as keratoconus.

With respect to measurement of peripheral refractive errors, it is well documented that myopic eyes experience relative hyperopia at the peripheral retina in the horizontal meridian (Atchison et al., 2006; Lin et al., 2010). Peripheral refractive errors have been measured with a number of techniques including retinoscopy, autorefraction, photorefraction and aberrometry. The most frequently used instrument is the Shin Nippon autorefractor as its open-field designs allows for relatively easier measurement of peripheral refractive errors. There have also been specially designed instruments such as the BHVI Eye Mapper (Fig. 33.6) that enable rapid measurement of peripheral refractive errors, but these are presently available only in research facilities. It is hoped that the lenses designed for peripheral retinal defocus management are able to sufficiently reduce hyperopic defocus and / or induce myopic defocus across the majority of myopes without the need to custom measure and fit each individual.

Careful consideration should be given to the history and assessment of the ocular health status as conditions such as allergic conjunctivitis and vernal conjunctivitis are more frequently seen in children and may be exacerbated by lens wear. Examination of the anterior segment of the eye should include lid eversion and examination of the upper tarsal conjunctiva.

In addition, assessment of the ocular health of a myope should include an assessment of the retina at baseline and at regular intervals thereafter. Retinal examination should preferably be under dilation to rule out or document any peripheral retinal changes / degeneration that are frequently seen in myopic eyes.

TABLE 33.2 Summary of Evidence for Myopia Control with Spectacle Lenses

Lens Type	Authors	Control Group	Percent Reduction vs Control	Duration of Study (years)	Significant Difference Between Groups	Difference in Dioptric Value (D)	Evidence for Myopia Control
Progressive addition spectacles	Leung & Brown (1999)	Spectacle	38 (+1.50 D) 46 (+2.00D)	2	Yes	0.47 0.57	Slow progress of myopia
	Edwards et al. (2002)	Spectacle	11	2	No	0.14	
	Yang et al. (2009)	Spectacle	17	2	Yes	0.26	
	Gwiazda et al. (2003)	Spectacle	13	3	Yes	0.20	
	COMET2 (2011)	Spectacle	24	3	Yes	0.28	
	Berntsen et al. (2012)	Spectacle	33	1	Yes	0.18	
Executive Bifocals	Cheng et al. (2014)	Spectacle	42 (+1.50 D) 51 (+1.50 D, 3 Δ BI)	3	Yes	0.81 1.05	Slow progress of myopia
Peripheral defocus management	Sankaridurg et al. (2010)	Spectacle	15 (Type III)	1	No	0.12	No evidence for overall group
Peripheral defocus plus Progressive addition	Hasebe et al. (2014)	Spectacle	14 (+1.00D) 20 (+1.50D)	2	No	0.19 0.27	Slow progress with higher add

COMET2 = Correction of Myopia Evaluation Trial 2.

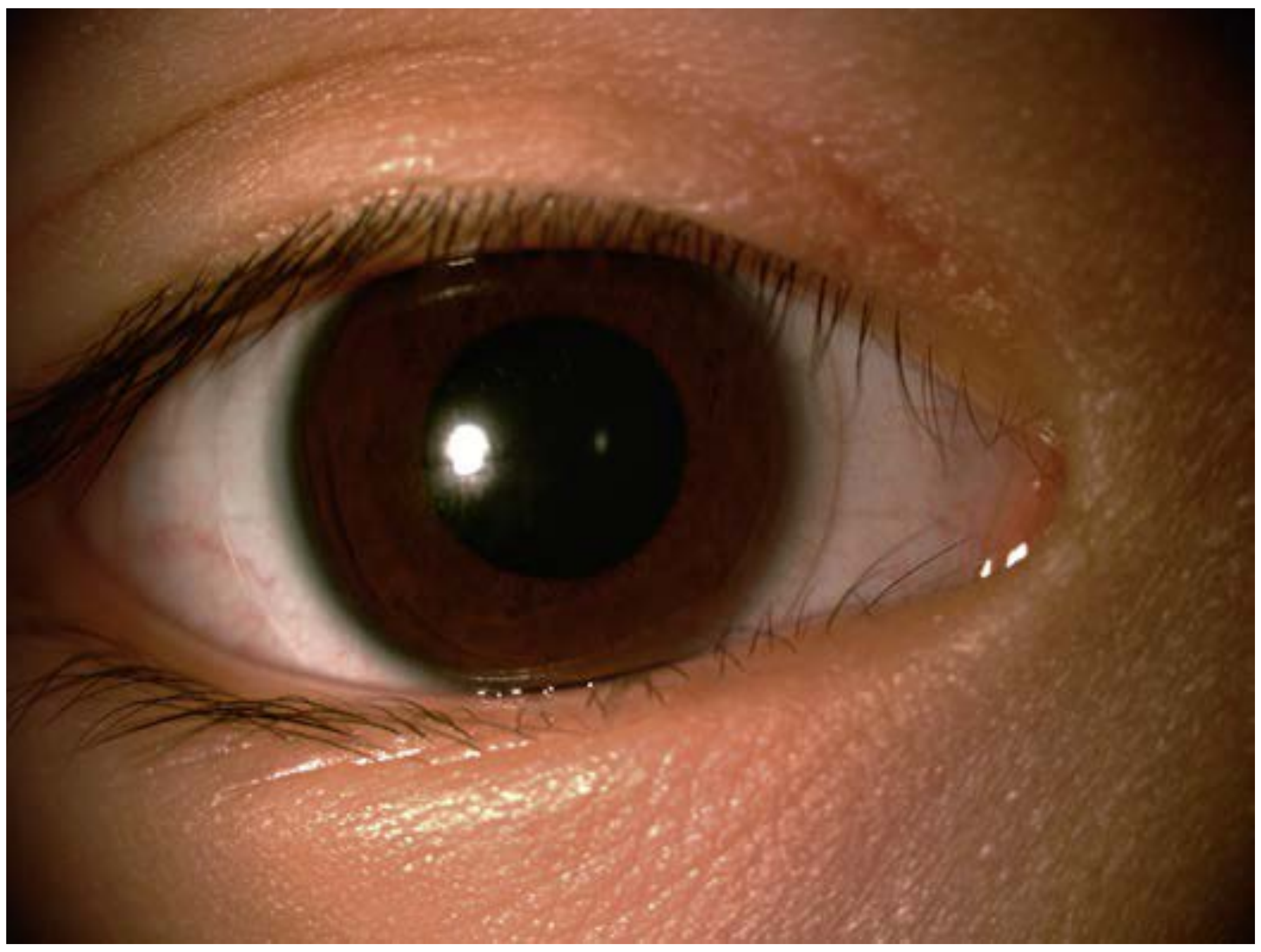


Fig. 33.5 A well-centred silicone hydrogel contact lens on the eye of a child.

LENS SELECTION AND FITTING

The initial selection of the distance power of the lens is ideally based on the cycloplegic spherical equivalent refractive error with appropriate adjustments for vertex distance correction. The currently available mypoia-control lens designs are spherical lenses and can correct only low amounts of astigmatism.

If the individual, or in the case of a child, if the parent / guardian, is motivated to control the progression of myopia, lenses that have been shown to slow myopia can be considered. At the present time, MiSight® is the only commercially available contact lens that is directed towards myopia control, but its availability is restricted to few countries. Use of lenses such as bifocal / multifocal lenses for myopia control would be deemed to be off-label and hence consideration should be given to the local regulations with respect to such use. Also, the situation must be fully explained to the wearers and / or their carers. The lens material will be either hydrogel or silicone hydrogel and should be considered for daily wear, and preferably lenses will be daily disposables in younger individuals and children. With respect to the lens design, with the exception of lenses that extend the depth of focus, other lenses have a number of zones, with one or more zones directed to a power that is the distance power of the eye and the remaining zones having a relatively plus power compared with the distance power zones. Where applicable, it is preferred that the manufacturer's guidelines are followed with respect to choosing a lens design that is appropriate for the need of the individual. In some instances the manufacturer may require the practitioner to choose the appropriate lens power and design based on the risk profile of the individual. However, as many of the lenses are multifocal in nature, similar to lens fitting in presbyopes, the wearer may experience fluctuations in image quality based on the zone size, pupil size, illumination levels and object distance; therefore, the practitioner may have to, in certain situations, optimize the visual performance.

Prior to any adjustments to the lens power based on visual performance, the lens on the eye should be evaluated for fit. The lens should be well centred with adequate limbal coverage and minimal movement. Any decentration or excessive movement of the lens may result in (a) fluctuating vision and / or (b) poor vision due to induced aberrations.

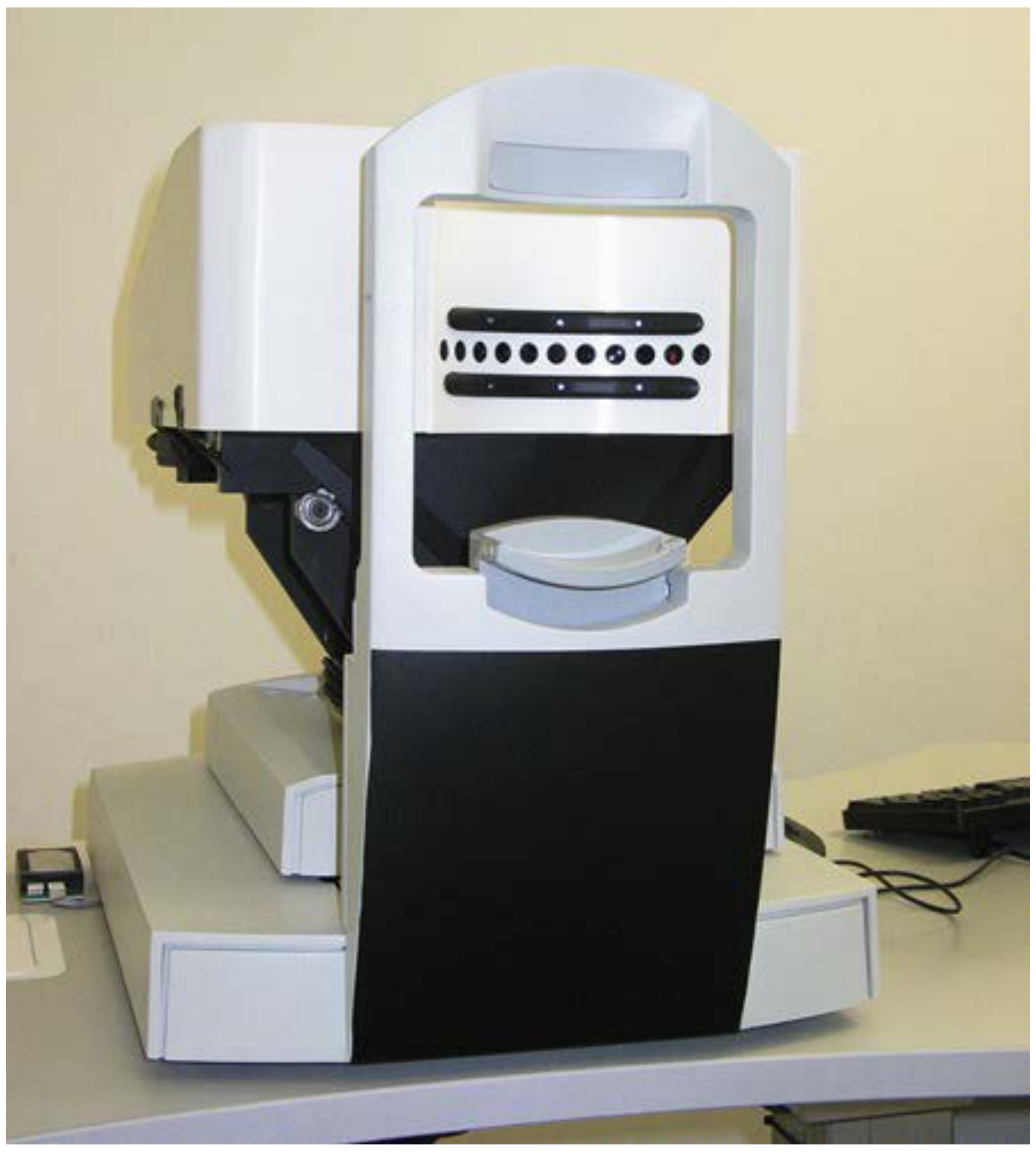


Fig. 33.6 The BHVI Eye Mapper used for rapid measurement of central and peripheral refractive errors. (Courtesy of Brien Holden Vision Institute.)

Once the lens fit on-eye has been evaluated, the visual performance needs to be carefully assessed with a careful overrefraction. Although the first instance of wearing a multifocal lens may be unsettling, a vast majority of lens wearers adapt to the vision rapidly and, therefore, there should be an adaptation time of approximately 15 minutes or more before visual performance is evaluated. It is also advisable to allow the wearer to experience a range of situations (e.g. walking down a corridor, looking at a distant view, reading or near tasks) before any evaluation is conducted. As a rule, an overrefraction should be performed using a trial frame (always recommended in young wearers) rather than a phoropter, as any vertex distance variations, tilted eye / face position behind the phoropter may alter optical performance. Also, for a person behind a phoropter, it is not possible to adopt the head and eye position that naturally occurs for near tasks (i.e. head bowed down) and, therefore, there may be additional variations introduced for near tasks. As with any multifocal lens fitting, a small dioptric change such as ±0.25 D may lead to a significant change in visual performance and thus needs to be carefully approached. Ideally, one should stay close to the cycloplegic or objective refractive error. If a change is needed it should be based on a significant improvement in visual acuity (one line or more) rather than subjective impressions of better clarity.

HANDLING OF LENSES

Many eye-care practitioners are likely to be experienced in fitting teens or older individuals with contact lenses but not younger children, as this group normally does not seek contact lenses except in certain special circumstances such as paediatric aphakia, corneal scars, keratoconus, amblyopia therapy, post-surgical lens fitting etc.

It is clear from the literature that children aged 7 years and beyond are capable of handling and wearing most contact lens modalities (Walline et al., 2008; Li et al., 2009; Sankaridurg et al., 2011). A small difference in total chair time for children compared with teens was found to be due to the longer time spent teaching children lens insertion and removal (Walline et al., 2007b). A recent study found that teenagers were able to confidently handle contact lenses, with a significant difference in subjective rating for quality of life, satisfaction, appearance, activities, etc. compared with those wearing spectacle lenses (Plowright et al., 2015).

Where children are involved, it is common practice to train both the carer and the child in lens insertion and removal techniques. However, it is equally important to ensure that the child is fully capable of independently managing all other aspects of lens wear, including disinfection and care procedures. In addition, they should also be educated in dealing with common problems such as an irritated and / or red eye, lens mislocation, etc. before they are discharged from the clinic.

Continuing Care and Complications

It is advisable to examine the individual within the first few weeks of the lenses being dispensed to ensure that they are comfortable with lens wear and, in the case of children, to ensure that their / their carers' expectations with respect to lens wear are being met.

Thereafter, all lens wearers must be evaluated at regular intervals, but even more so in young and progressing myopes, as any progression of myopia is likely to result in blurred vision. With children, follow-up visits at 3-monthly intervals with no more than 6-month periods between visits is preferable. At the follow-up visits, any drop in visual acuity of one line or more, or overrefraction greater than 0.25 D, would require a refraction to determine progression and change of lenses as needed.

In children, in the short term, the most frequently observed clinical finding was corneal staining (ranging from 6 to 21%) (Li et al., 2009). Over a slightly longer duration (i.e. 2 years) and involving wear of silicone hydrogels on a daily wear basis, mechanical events such as contact lens papillary conjunctivitis, superior epithelial arcuate lesions and corneal erosions were the most frequently seen problems. There were no serious incidents reported. Corneal infiltrative events were few and mostly asymptomatic (Sankaridurg et al., 2013).

Conclusion

It has been shown that contact lenses can serve as a platform for a number of optical approaches aimed at slowing eye growth in myopia. The feasibility of myopia control contact lenses to slow the progress of myopia has been substantiated with a number of independent clinical trials. These treatments are generally directed at children and young adults as it is during those years, that myopia is seen to progress rapidly. Contact lenses are well accepted, shown to improve esteem and quality of life compared with spectacles, generally proven to be safe for use in children and are an effective mode of delivering myopia control strategies. The key to prescribing myopia control contact lenses is to (a) understand, appreciate and monitor the expectations of the individual with respect to myopia control strategies; (b) ensure that the individual and / or carers fully understand the advantages and disadvantages associated with contact lens wear and myopia control strategies; (c) choose a strategy that fits with the expectation of the individual and / or carers; (d) continuously monitor to ensure success in lens wear; and (e) emphasize at all times the need for cleanliness, hygiene, good lens care and daily or regular replacement, especially where children are involved.

Access the complete references list online at http://www.expertconsult.com.

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34

Diabetes

CLARE O'DONNELL

Introduction

Diabetes mellitus is one of the most common systemic diseases in the world and it occurs when the pancreas does not produce enough insulin or when the body cannot effectively use that insulin. Hyperglycaemia (elevation of blood glucose concentration) is a common effect of uncontrolled diabetes and over time this leads to damage to, and dysfunction and failure of many of the body's organs including the eye. It is classified into two main types: type 1 (previously known as insulin-dependent) diabetes and type 2 (formerly known as non-insulin-dependent) diabetes. The prevalence of diabetes is increasing and, in 2014, an estimated 9% of adults aged 18 years and older had diabetes. Type 1 diabetes accounts for approximately 10% of primary diabetes, whereas type 2 diabetes accounts for 90% (World Health Organization, 2015).

Although the retinal complications of diabetes are well documented, what is perhaps less well appreciated is that poorly controlled diabetes can adversely affect all ocular tissues. In order to understand the possible effects of diabetes on the eye during contact lens wear, it is necessary to consider how the anterior eye of diabetic patients may differ from that of non-diabetic patients.

The Anterior Eye

Retinopathy is the ocular complication that most commonly causes loss of vision in diabetic patients (Fig. 34.1); however, various abnormalities affecting the anterior eye have also been described (see O'Donnell and Efron, 2012 for review).

ORBIT

Patients with poorly controlled diabetes are more susceptible to bacterial and fungal infections of the orbit than are non-diabetic individuals. Mucormycosis is a rare but potentially fatal fungal infection and those affected may present with ophthalmoplegia, loss of vision, pain and proptosis.

EYELIDS

Xanthelasma is a condition in which yellow deposits appear on the eyelid, and is thought to be due to abnormalities in lipid metabolism. Xanthelasmata can occur at an earlier age and more frequently in patients with diabetes than in non-diabetic patients (Waite and Beetham, 1935) (Fig. 34.2).

Ptosis can be an early sign of undiagnosed diabetes, the underlying cause being chronic tissue hypoxia. Blepharitis, styes and meibomian cysts are also more commonly found in the diabetic population.

TEAR FILM

Studies suggest that diabetic patients complain of dry eyes more frequently than do non-diabetic individuals (Ramos-Remus et al., 1994; Akinci et al., 2007). Reduced tear secretion is often found in association with diabetes, and is perhaps related to dysfunction of the autonomic nervous system serving the lacrimal gland (Ramos-Remus et al., 1994; Dogru et al., 2000). Dogru et al., (2000) reported that tear break-up time is significantly lower in diabetic patients who have decreased corneal sensitivity. Increased levels of secretory immunoglobulin A, lysozyme and glucose (Gassett et al., 1968) have been observed in the tear film of patients with diabetes. It has been suggested that increased tear glucose concentration could promote lens spoilation and the growth of microorganisms in diabetic contact lens wearers. The influence of high tear glucose levels may alter the biomechanical properties of the cornea in diabetic patients.

CONJUNCTIVA

Microaneurysms, capillary proliferation and vessel dilations have been noted in the conjunctivae of diabetic patients. These features are not unique to diabetes; they can occur in association with other systemic diseases such as hypertension and arteriosclerosis (L'Esperance and James, 1983). Conjunctival oxygen tension may be reduced in patients with advanced diabetic eye disease compared with those with milder retinal changes (Isenberg et al., 1986). Kruse et al. (2006) suggested that diabetic patients have an increased risk of developing acute infectious conjunctivitis and Dogru et al. (2000) noted a reduction in goblet cell density in diabetic eyes.

CORNEA

The ultrastructural and biochemical status of the cornea is altered in patients with diabetes (McNamara, 1997; O'Donnell and Efron, 1998; Wiemer et al., 2007, O'Donnell and Efron, 2012); some of the changes that have been described are summarized in Table 34.1.

Below is an account of alterations to the structure and function of the cornea that are of more direct clinical relevance to contact lens wear.

Epithelium

The corneal epithelium is known to be particularly susceptible to mechanical trauma in diabetic patients (O'Leary and Millodot, 1981). Recurrent corneal epithelial defects, superficial punctate keratitis and prolonged epithelial healing rates have also been reported, particularly after ophthalmic surgery.

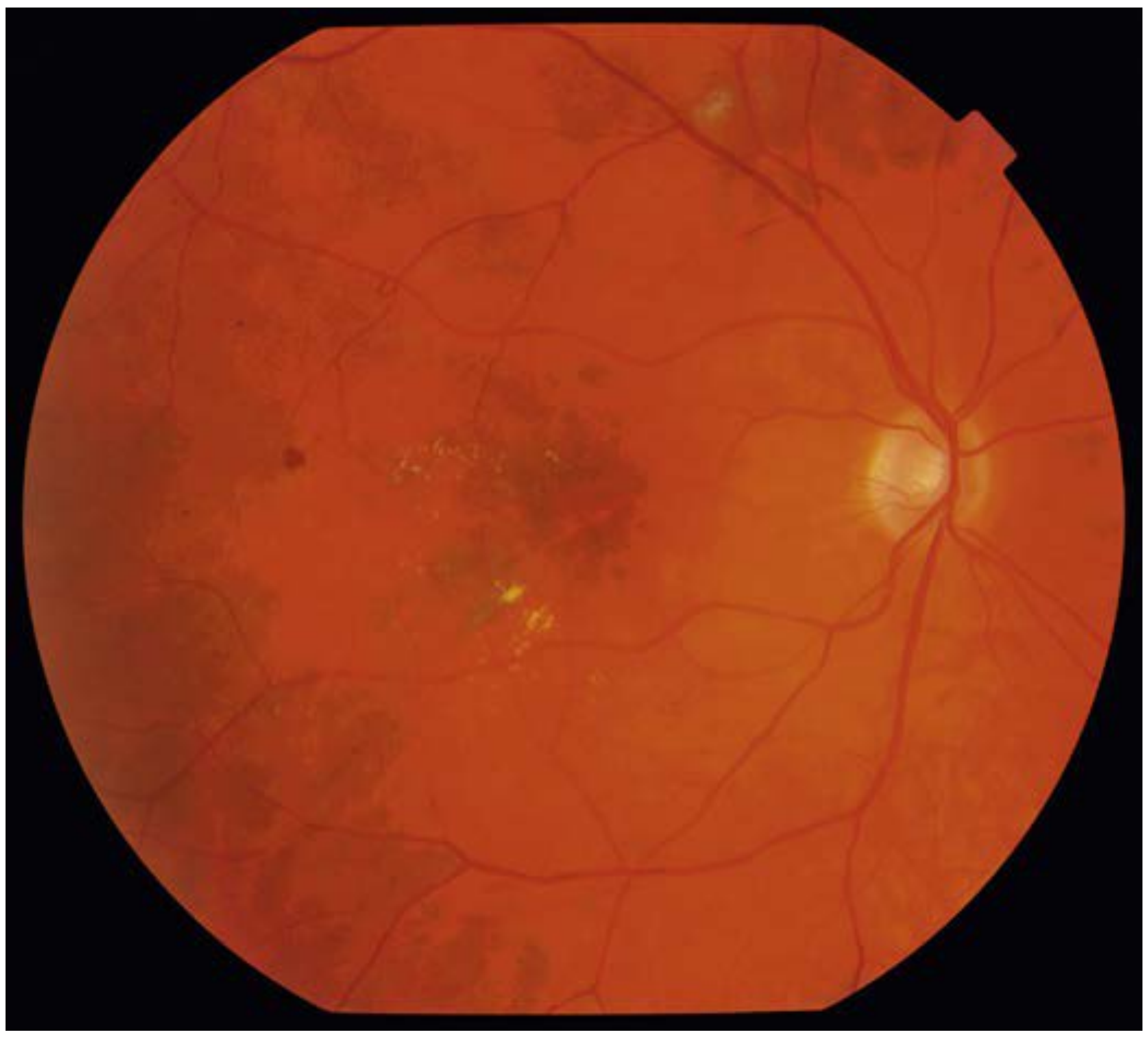

Fig. 34.1 Diabetic retinopathy.

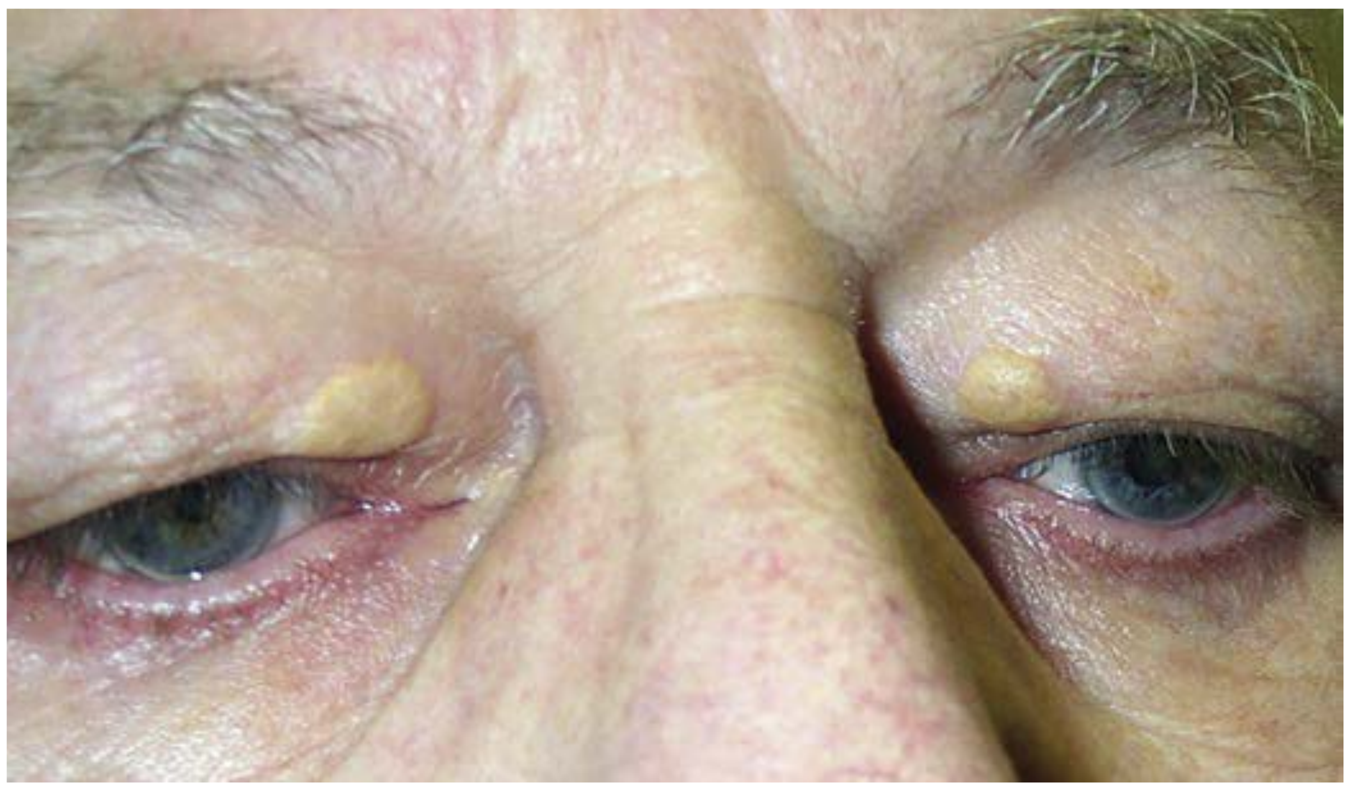

Fig. 34.2 Diabetic patient with bilateral xanthelasmata.

Inadequate adhesion of cells to an abnormal underlying basement membrane, reduced corneal oxygen consumption and reduced corneal sensitivity have been implicated in many of the corneal epithelial complications observed.

Corneal Nerves

Diabetes can cause a significant reduction in corneal sensitivity (O'Leary and Millodot, 1981; Pritchard et al,. 2012). This sensory deficit is thought to occur owing to a diffuse polyneuropathy. The extent of the reduction appears to relate to the duration of the diabetes, the age of the patient and the degree of diabetic metabolic control. Corneal nerves play an important role in the maintenance of a healthy cornea by providing a trophic influence and warning of corneal insult. Reduced corneal sensitivity has been linked with the development of corneal ulcers in diabetic patients (Lockwood et al., 2006), and it is generally accepted that contact lens wear should be approached with caution in any patient with corneal hypoaesthesia. Such patients should be advised to remove lenses and to seek advice if they experience any discomfort.

Corneal confocal microscopy has been used to evaluate the alterations that occur in patients with diabetes (Tavakoli et al., 2012). Researchers have reported structural changes to corneal nerves (Malik et al., 2003; Kallinikos et al., 2004) and others have related these changes to the reductions observed in corneal sensitivity (Rosenberg et al., 2000). The alterations in nerve structure appear to be more pronounced in patients with diabetic polyneuropathy (Malik et al., 2003; Dehghani et al., 2014) and patients with diabetic retinopathy (Mocan et al., 2006). Quattrini et al. (2007) showed that corneal confocal microscopy can quantify small-fibre damage rapidly and non-invasively and can detect earlier stages of nerve damage compared with currently used techniques, suggesting this potentially makes it ideal to diagnose and assess the progression of diabetic neuropathy.

TABLE 34.1 Biochemical and Structural Changes Associated with Diabetes

Structure	Changes
Tears	Decreased secretion and instability Increased lysozyme Increased secretory immunoglobulin A Increased glucose concentration
Epithelium	Pleomorphism Increased cell size Thickened basement membrane Decreased adhesion of cells to basement membrane Decreased penetration of anchoring fibrils into stroma
Nerves	Decreased corneal sensitivity Structural alterations
Stroma	Increased thickness Glycosylation of collagen Increase in intermolecular spacing of collagen fibrils Increased autofluorescence
Descemet's layer	Folds Increased thickness
Endothelium	Polymegethism Pleomorphism Reduced Na-K-ATPase activity

Endothelium

Studies of corneal endothelial morphology in diabetic humans and animals have revealed increased levels of polymegethism and pleomorphism (Fig. 34.3).

Most researchers have failed to demonstrate significant reductions in endothelial cell density among diabetic patients (O'Donnell and Efron, 2004a), which contrasts with the findings of Lee et al. (2006).

The appearance of folds in Descemet's membrane has been reported in diabetic patients (Waite and Beetham, 1935) (Fig. 34.4). When associated with diabetes, vertical folds often appear in the central corneal endothelium of both eyes. Folds due to diabetes appear to be enduring, unlike folds due to contact lens-induced corneal oedema, which disappear after lens removal (O'Donnell et al., 2001).

Corneal Hydration Control

Corneal thickness is often increased in diabetic patients (Skaff et al., 1995; McNamara et al., 1998; Lee et al., 2006). Abnormal function of the corneal endothelium has been postulated as the cause, perhaps as a direct result of the accumulation of glucose and sorbitol (McNamara, 1997).

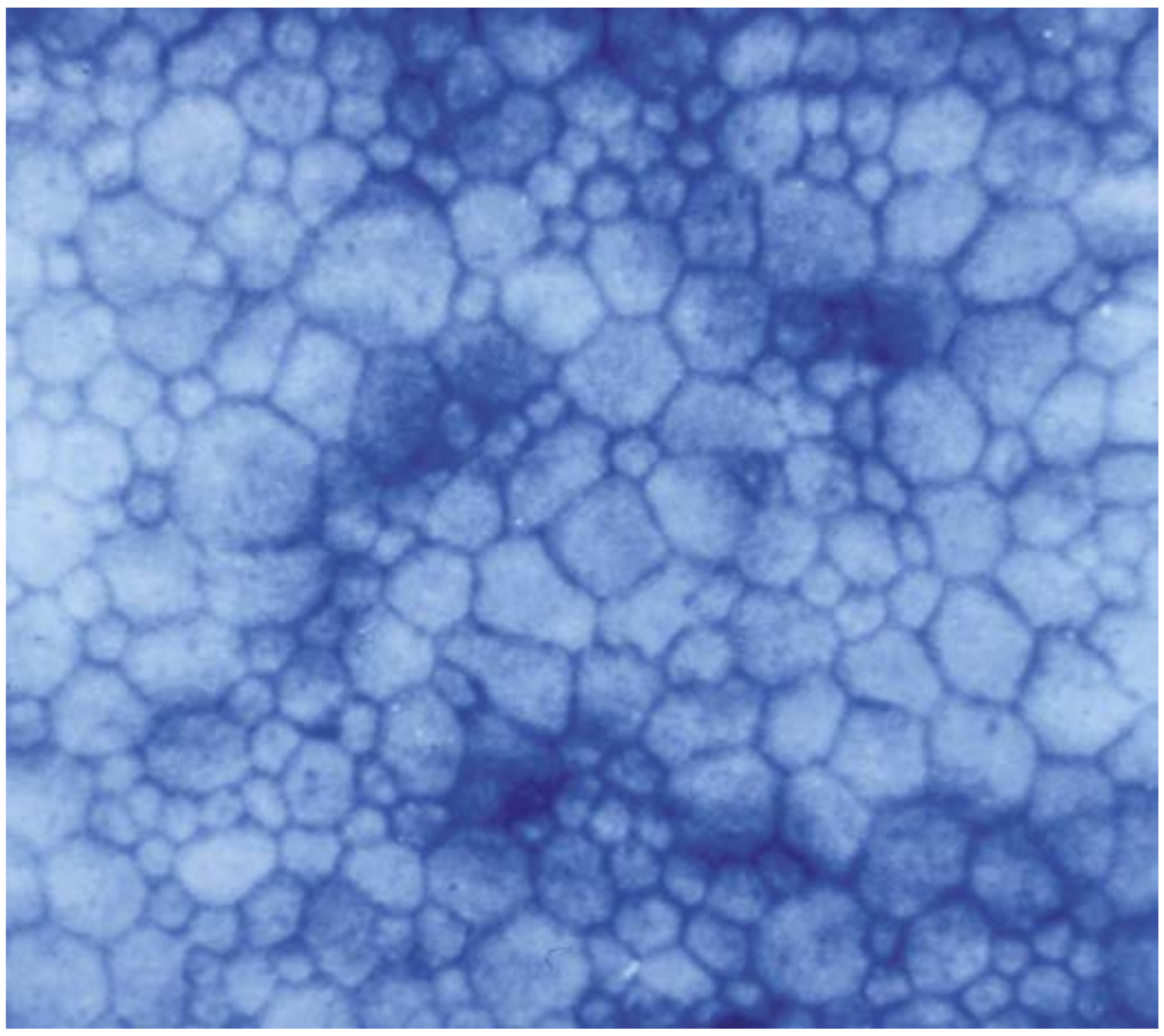

Fig. 34.3 Endothelial polymegethism.

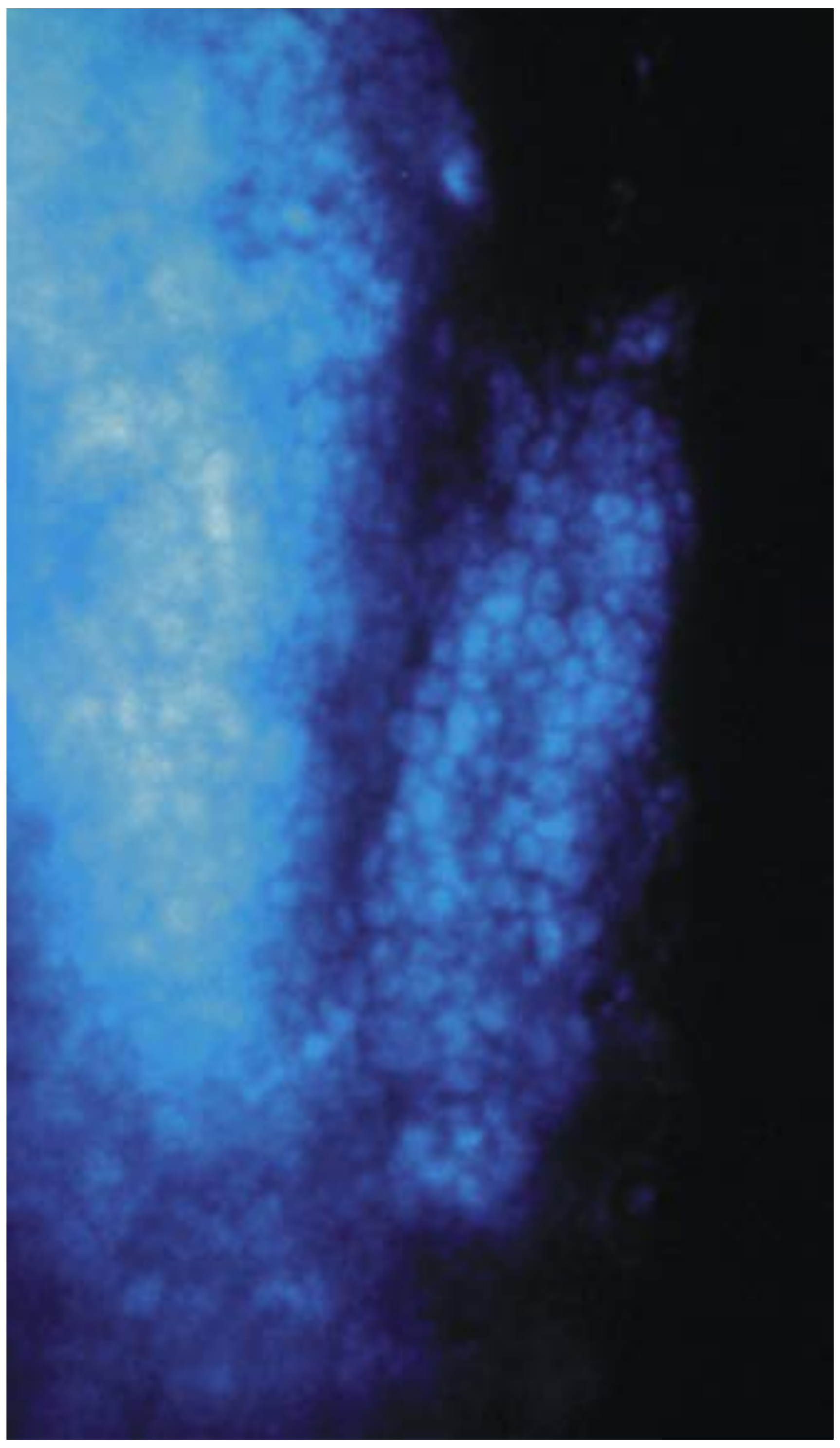

Fig. 34.4 A single diagonally oriented endothelial fold. (Courtesy of Steve Zantos.)

Increased corneal epithelial and endothelial permeability to fluorescein has been reported in patients with diabetes compared with non-diabetic control individuals. It has been suggested that the limiting layers of the diabetic cornea function normally during everyday conditions, but may have a reduced ability to cope with the stress induced by ophthalmic surgery or long-term contact lens wear (McNamara, 1997). In a study analysing the effects of soft contact lens wear in diabetic and non-diabetic control individuals, Leem et al. (2011) concluded that corneal thickness and endothelial cell density are more affected by diabetes mellitus whereas corneal endothelial cell morphology is more affected by contact lens usage.

Investigators have used pachymetry to monitor the recovery response to oedema induced by contact lenses of low oxygen transmissibility. This approach has demonstrated reduced absolute corneal swelling (McNamara et al., 1998; O'Donnell and Efron, 2006) and prolonged recovery times from oedema in diabetic patients compared with normal controls. Since the rate of recovery from corneal oedema is reduced in diabetic patients, it has been suggested that care should be taken when prescribing contact lenses for such patients. However, it could be argued that these studies do not identify any obvious problems arising in diabetic patients wearing contact lenses with high oxygen transmissibility on a daily-wear basis.

Microbial Keratitis

Schein et al. (1989) found that diabetic patients using contact lenses have an increased risk of developing microbial keratitis, although the magnitude of the increased risk was not stated. Keay et al. (2009) evaluated the clinical signs, symptoms and the ocular and systemic comorbidities in a large series of contact lens-related microbial keratitis. Their study showed that microbial keratitis was more common in those with poor general health. Diabetic contact lens wearers should be advised to seek immediate advice if they develop a painful red eye or other symptoms suggestive of corneal ulceration.

IRIS

Iris changes associated with diabetes include the deposition of glycogen vacuoles in the iris pigment epithelium, pigment dispersion, iris atrophy and iris neovascularization.

PUPIL

Pupil size and pupil reactions may be altered in diabetic patients with poor metabolic control. The pupil may be more difficult to dilate in diabetic patients with neuropathy.

LENS

It has been suggested that diabetes-induced changes occurring in the aqueous humour, cornea and crystalline lens could play a role in refractive fluctuations although there is uncertainty about the exact mechanism of such changes. Changes in refractive error in uncontrolled or undiagnosed diabetic patients have been reported. Huntjens et al. (2012) showed that short-term fluctuation in blood glucose levels did not induce short-term changes in refractive error, ocular aberrations or the anterior ocular biometric parameters, although another study showed that diabetic patients demonstrated smaller anterior chamber depths, more curved lenses, greater lens thickness and lower lens equivalent refractive index (Adnan et al., 2015). A reduced amplitude of accommodation has also been shown in individuals with diabetes when compared with age-matched controls, suggesting that individuals with diabetes will experience presbyopia earlier in life than people without diabetes (Waite and Beetham, 1935; Adnan et al., 2014). Cataracts are a well-known cause of visual impairment in people with diabetes.

PANRETINAL PHOTOCOAGULATION

Corneal complications such as reduced corneal sensitivity, corneal erosions and keratitis have been reported following panretinal photocoagulation (PRP). (This procedure has also been associated with other complications such as visual field loss, persistent mydriasis, iritis, iris atrophy, lens opacities, shallowing of the anterior chamber and accommodative palsy.) Corneal endothelial cell loss after PRP has also been documented.

Ocular Response to Contact Lenses

Given the alterations to the anterior segment that accompany diabetes, an important issue to be addressed is whether or not contact lenses should be prescribed for diabetic patients for refractive correction. Reports of ocular complications in diabetic patients who wear contact lenses do exist; however, a number of these concern patients with advanced diabetic eye disease using extended-wear contact lenses.

The results of a prospective, controlled study have demonstrated that daily-wear soft contact lenses can be a viable mode of vision correction for patients with diabetes. O'Donnell et al. (2001) and March et al. (2004a) suggest that practitioners should not expect to see adverse clinical signs in diabetic contact lens wearers that are any different from those seen in non-diabetic lens wearers. If adverse signs are detected in a diabetic lens wearer, they should not be attributed solely to the fact the patient has diabetes, and the predisposition of the diabetic patient to corneal infection should always be borne in mind.

SPECIAL CONSIDERATIONS

Roughening of the fingertips caused by home blood glucose monitoring could lead to damage to the lens surface during cleaning, and patients should therefore be reminded to inspect contact lenses for damage prior to lens insertion. Fingernails should be kept short and smooth to reduce the risk of corneal erosion (O'Donnell and Efron, 1998).

PRESCRIBING CONTACT LENSES

Although there are established trends in contact lens prescribing for the general population, clinical opinion is divided as to which type of contact lens is most appropriate for diabetic patients. In view of the fragility of the corneal epithelium, rigid contact lenses were previously not recommended for diabetic patients since corneal abrasion occurs more frequently with these lenses. However, rigid lenses do have certain advantages over soft lenses. The likelihood of toxins and potential pathogens becoming trapped beneath the lens is reduced with a rigid lens compared with a soft lens, and rigid lenses are also more durable and less prone to tearing or splitting.

The results of a survey conducted in the UK indicated that practitioners believed that rigid lenses are the safest form of contact lens for diabetic patients (Veys et al., 1997). However, this survey was conducted prior to the availability of silicone hydrogel contact lenses. The reason for rigid lenses being favoured for diabetic patients was a perceived reduced risk of infection with these lenses compared with soft lenses. Practitioners stated that important factors to be considered when fitting contact lenses to diabetic patients include the degree of metabolic control and the contact lens wear time.

COMPLIANCE

O'Donnell and Efron (2004b) investigated the notion that diabetic contact lens wearers may represent a special group displaying higher levels of compliance with their lens care regimen as a result of learned behaviour relating to maintenance of their diabetic condition. To test this hypothesis, a prospective, single-centre, controlled, masked study was performed whereby 29 diabetic contact lens patients and 29 non-diabetic control individuals were issued with disposable contact lenses and a multipurpose lens care regimen. All participants were given identical instruction on lens care and maintenance. Compliance levels were assessed at a 12-month aftercare appointment by demonstration and questionnaire. Twenty-four different aspects of compliance were scored, 12 by observation and 12 by questionnaire report, of which only two showed a significant difference between the diabetic and control groups. Although the combined population of contact lens wearers was generally compliant, there were examples of non-compliance in both groups. Neither the duration of diabetes nor the degree of metabolic control appeared to have a significant effect on compliance. The results suggest that eye care practitioners cannot assume that diabetic patients will be more compliant with contact lens care and maintenance than non-diabetic patients.

Glucose Sensing in the Anterior Eye

Since tear glucose concentration has been shown to mirror blood glucose concentration, it has been proposed that the measurement of tear glucose concentration could be used to monitor metabolic control non-invasively in diabetic patients. As contact lenses are bathed in tears, it has been suggested that measurement of tear glucose concentration could be carried out using contact lenses with glucose-sensing properties. However physiological factors mitigate against the use of tear glucose measurement as a viable surrogate for blood glucose measurement. First, the concentration of glucose in the tears is much less than that in the blood, which in broad terms means that a tear glucose sensor must be much more sensitive than a blood glucose monitor. Second, changes in tear glucose concentration lag behind changes in blood glucose concentration, and delay times between detection and read-out of 20 minutes or so have been recorded with some devices (Lane et al., 2006; Farandos et al., 2015). This is problematic in relation to acute glycaemic control where almost instantaneous determination of blood glucose levels may be required to implement timely strategies to avoid hypoglycemia.

Notwithstanding the limitations outlined above, there have been many attempts to develop contact lens glucose monitoring devices over the past decades. March et al. (1982) described the concept of using a scleral lens to determine aqueous humour glucose concentration as a surrogate measure of blood glucose concentration. They conceived of a scleral lens that houses a light source, polarizers, electro-optic units and a light detector which measures the optical rotation of the aqueous humour (March et al., 1982; Rabinovich et al., 1982). March et al. (2004b) used glucose-sensitive compounds in a hydrogel lens. An array of 488 nm light-emitting diodes in a hand-held device was used to illuminate the contact lens and the magnitude of the resultant fluorescent light was measured by a detector in the device. A correlation between the contact lens fluorescence and blood glucose concentration was demonstrated, albeit with the expected time lag.

March et al. (2000) investigated the possibility of using an intraocular lens impregnated with fluorescent compounds to monitor blood glucose concentration. Domschke et al. (2006) used a holographic sensor embedded in a daily disposable hydrogel lens. When glucose bound to components in the device, the colour of the light reflected off the hologram changed when illuminated by a laser. A trial of one patient showed a correlation between blood glucose concentration and the holographic signal. Chu and colleagues (2011) developed and tested an electronic biosensor embedded in a rigid contact lens on a rabbit eye. The biosensor showed a good correlation between the output current and glucose concentration. This concept was limited by a need for the lens to be wired to provide input voltage and output reading.

Although many of these examples demonstrate proof of concept, none of the devices has been commercialized, although the possibility of a contact lens sensor that is powered externally and permits wireless read-out using an auxiliary device has generated considerable interest from Google, Novartis and Microsoft (Otis and Parviz, 2015; Parviz and Tan, 2015).

Contact Lens Wear in Patients with Other Systemic Disease

Patients with any systemic disease known to adversely affect the anterior eye potentially face problems during contact lens wear. Conditions such as thyroid deficiency, hyperthyroidism, rheumatoid arthritis, atopic eczema, psoriasis and acne rosacea may affect suitability for contact lenses. In general, these conditions, when managed, do not contraindicate contact lens wear but may influence the lens type or the wear schedule selected. Patients with allergies can achieve success with contact lenses but may require more-frequent lens replacement or more-frequent aftercare examinations, as these patients are more susceptible to lens-induced discomfort and lid problems. Wolffsohn and Emberlin (2011) have suggested that daily disposable contact lenses can offer a barrier to airborne antigens. There is no contraindication to fitting contact lenses to patients who are human immunodeficiency virus (HIV)-positive, provided that the anterior eye is healthy. Practitioners should wear protective gloves if they have open skin lesions. If the patient has progressed to acquired immunodeficiency syndrome (AIDS), the increased risk of opportunistic infection should be considered and contact lens fitting approached with extreme caution.

CORNEAL SCARRING OR THINNING

Where a patient suffers from any condition resulting in an irregular corneal surface, contact lenses may prove to be the only practical method of vision correction. In such cases, rigid lenses are usually the first choice (O'Callaghan and Phillips, 1994). Careful slit-lamp examination together with a detailed history will alert the practitioner to those patients susceptible to corneal perforation.

KERATOCONJUNCTIVITIS SICCA

Patients with systemic conditions resulting in dry eye may require ocular lubricants, tear supplements, dietary and environmental modifications and ultimately punctal occlusion. As the successful wearing of any form of contact lens requires a well-lubricated surface, contact lens materials offering good wettability should be selected.

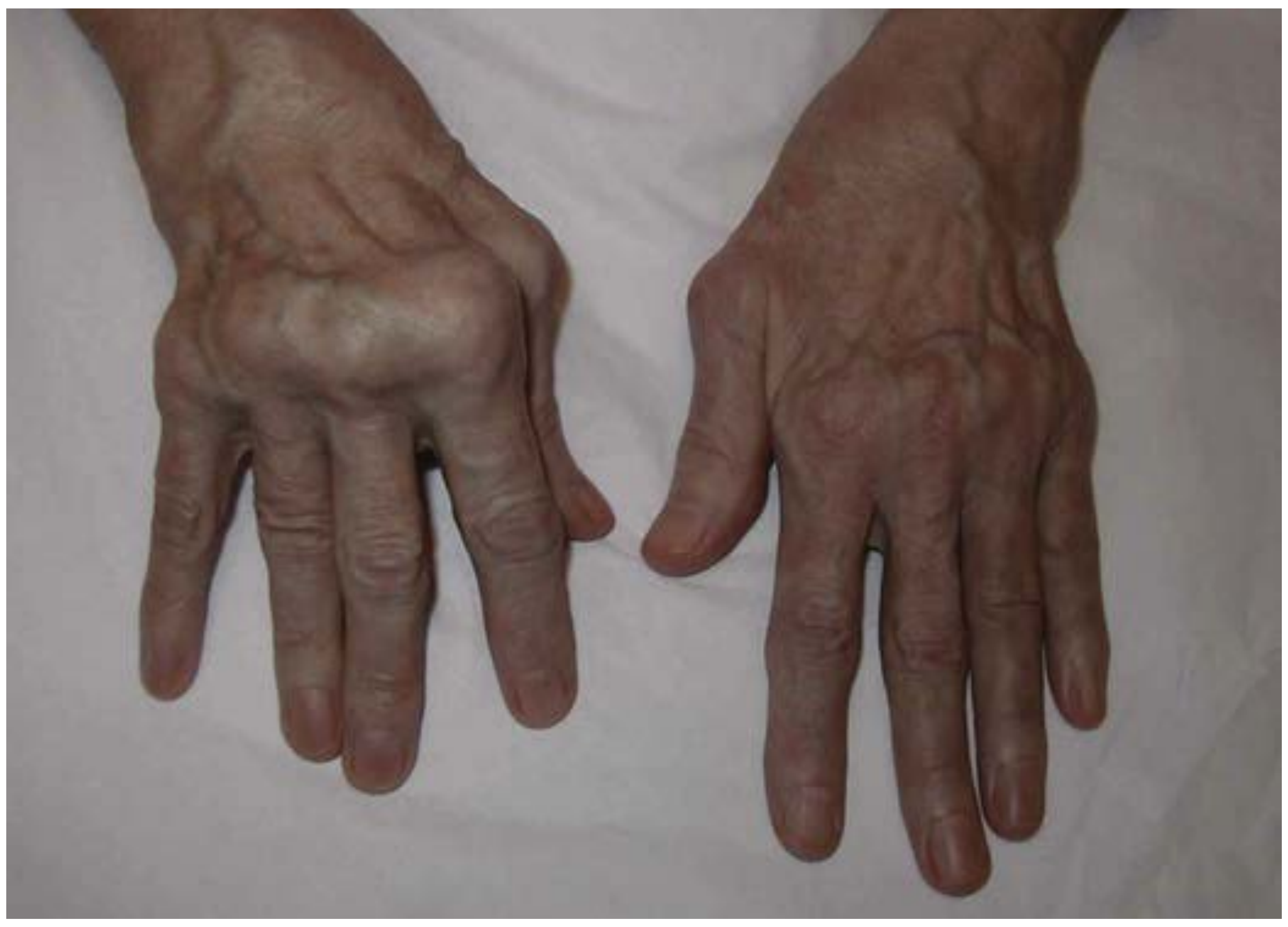

Fig. 34.5 Deformation of the knuckles and finger joints in a patient with rheumatoid arthritis.

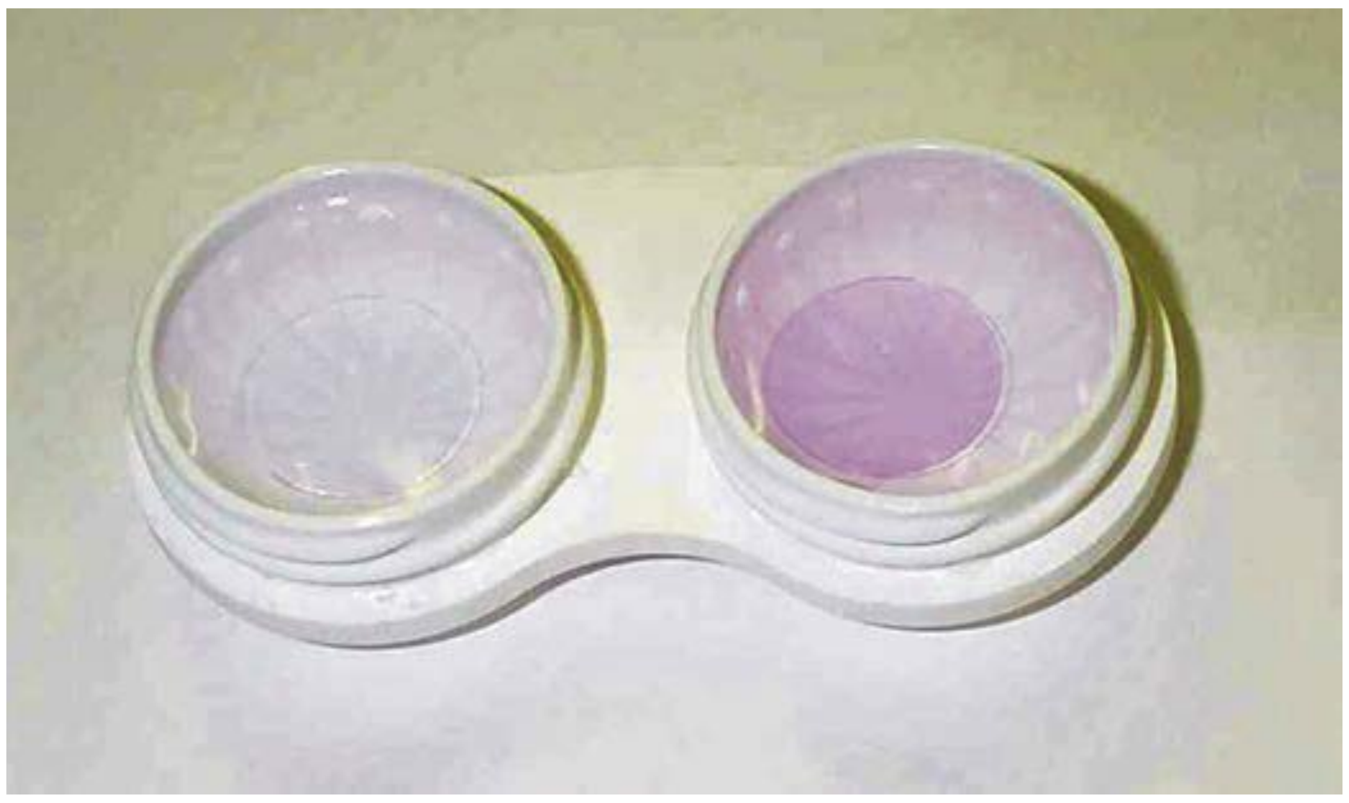

Fig. 34.6 Pink discolouration of hydrogel contact lenses (in the right side of the lens case) can be observed with medications such as rifampicin. The left side of the lens case contains an unaffected lens.

HANDLING PROBLEMS

Restrictions of mobility, as in rheumatoid arthritis or 'diabetic hand syndrome', may make the handling of contact lenses difficult (Fig. 34.5).

Patients should be encouraged to handle their own lenses whenever possible. When handling becomes impossible, a relative or carer may provide assistance, and periods of extended or continuous wear may be appropriate.

OCULAR SIDE-EFFECTS OF THERAPY

The ocular complications of both prescription and over-the-counter medications – such as decongestants, antihistamines and oral contraceptives – should be taken into consideration when contact lens wear is being considered. Possible side-effects of medications include dry eye, photosensitivity, alterations to pupil size or function, corneal and contact lens deposition, punctate keratopathy, subconjunctival haemorrhage and discoloration of contact lenses (Fig. 34.6).

Conclusion

When considering whether to proceed with contact lens fitting in patients with diabetes or other systemic disease affecting the anterior eye, the practitioner needs to conduct a risk–benefit analysis with the patient. Where an increased risk of ocular complications has been ascertained, the patient should be fully informed of the risks and the benefits of contact lens wear. The importance of the patient complying with recommendations for lens care and maintenance, wearing schedules and attending follow-up visits should be emphasized. A thorough understanding of the ocular and systemic history, careful examination during fitting and follow-up to exclude the possibility of external eye disease, and the use of superior contact lens products will increase the likelihood of success for all prospective contact lens wearers. Additionally, there is promise that in the future contact lenses manufactured from hydrogel polymers embedded with glucose-sensing agents or nanoscale digital electronic technology may be used by diabetic patients to help monitor their diabetic metabolic control less invasively.

Access the complete references list online at http://www.expertconsult.com.

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PART
6

Patient Examination and Management

PART OUTLINE

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35

History Taking

JAMES S W WOLFFSOHN

Introduction

History and symptoms are critical in determining whether an individual is suitable for contact lens wear, to aid selection and to inform management. The aim is to elicit relevant information comprehensively but in as concise a manner as possible, as time is limited in a clinical setting, but missing information can result in suboptimal clinical decisions. Clinical records have been found to underestimate actual care provided, suggesting record keeping is not always as comprehensive as it should be (Shah et al., 2010). A web-based survey, developed by the British University Committee of Contact Lens Educators (BUCCLE – which comprises of all the academic-based contact lens educators in the UK and Ireland), of 256 respondents with a wide range of experience, mainly from the UK and Eire, informed the recommendations in this chapter (Wolffsohn et al., 2015).

The objectives for a new patient include:

- to determine the suitability for contact lens wear based on:
  - an analysis of patient-specific indications and contraindications
  - a risk–benefit analysis for the individual patient
- to guide the patient as to the most suitable lens modality and type based on:
  - their lifestyle (including occupation)
  - aspirations for lens wear and financial outlay
  - the outcome of their ocular health examination
  - refraction
  - binocular vision
- to ensure that expectations are realistic, such as:
  - visual outcomes
  - range of clear focus in presbyopes
  - myopia control in children
  - wearing time
  - lens care requirements
- to collate baseline patient information:
  - to justify clinical decision-making
  - to allow future changes to be examined at aftercares
- to ensure that the compliance implications of contact lens wear are communicated.

Pointer (2014) examined the open question regarding issues with the patient's eyesight that is typical at the beginning of a consultation and demonstrated that uninterrupted statements of greater than 30 seconds were unlikely to provide useful additional information. How a contact lens consultation history and symptoms is conducted will depend on whether it is an initial fitting, where past history, motivation and intended wearing pattern and environment will be the focus, or an aftercare session, where symptoms, changes in health and compliance aspects are foremost. Hence 'history and symptoms' in an initial questioning changes to 'symptoms and (changes in) history' for an aftercare session. Comprehensive capture of relevant information in a limited time will require a structured approach, ability to differentially diagnose and appropriate use of abbreviations.

Indications and Contraindications for Contact Lens Wear

Contraindications are often interpreted as a reason not to fit contact lenses, but in most cases, with reflection on the management of the condition or a change in contact lens choice, successful and safe wear may be achieved.

Patients with compromised ocular health such as meibomian gland disease (Nichols et al., 2011), low tear stability (DEWS, 2007) or recurrent epithelial erosion need the condition to be managed before soft or corneal RGP lenses are fitted, but therapeutic lenses could be part of that management in extreme cases. Poor tear film can be exacerbated by contact lens wear. This is due to the thickness of lenses relative to the tear film and the lens material or design's interaction with the ocular surface and adnexa (such as the eyelids) changing the composition of the tear film through stimulating inflammation and binding to protein and lipids (Mann and Tighe, 2013).

As patient compliance with practitioner instruction will be a major concern in patient management, it is important to judge the prospective patient's ability to understand the full implications of lens wear. It is also important that the patient's expectations that drive motivation are realistic and achievable. A particularly exacting personality type may find the adaptation period and the initial learning of handling techniques too intrusive and outweigh the overall benefits of lens wear. Manual dexterity to insert and remove lenses and maturity, mental capacity or willingness for compliant use may also increase the risks of wear beyond the potential benefits.

It is debatable whether the financial aspects of not only the fitting, but also the continuing clinical care and the ongoing costs of lens care solutions and lens replacements should be taken into consideration. Fitting lenses to a patient without the financial means to care for them will inevitably lead to non-compliance and increase the potential for adverse events to occur. However, presumed compliance by an eye-care practitioner is known to be a poor indicator of real compliance (Bui et al., 2010) and the patient's financial situation is rarely actually known.

It is important to judge the motivation to wear contact lenses and the personality type of the potential wearer. Contact lenses are considered to give a more normal cosmetic appearance and may contribute significantly to overall appearance, particularly when the refractive error is high. In addition, there are cases where lenses can be used specifically to conceal significant cosmetic defects such as iris anomalies, corneal opacities, inoperable squint or microphthalmos. Also if patients have extremely flat, steep or irregular corneas or the ocular surface needs protection then therapeutic contact lenses may be appropriate, such as scleral lenses.

History-taking Structure

Traditionally ophthalmic history taking would be structured so as to include the following elements.

REASON FOR VISIT

The reason for the visit should be ascertained. Reasons include the motivation for lens wear including cosmesis, scheduled aftercare (which may also report symptoms) or unscheduled visit due to symptoms. The management of symptoms includes the determination of any underlying pathology through differential diagnosis, optimization of lens fit if inadequate and finally alteration of lens features such as material, replacement frequency, care regimen or other factors for example the use of artificial tears, nutrition and environmental modifications (Papas et al., 2013). Various mnemonics have been suggested for the investigation of pain in the medical literature – such as LOFTSEA (location, onset, frequency, type, self-treatment, effect on patient, associated symptoms), SQITARS (site and radiation, quality, intensity, timing, aggravating factors, relieving factors, secondary symptoms) and SOCRATES (site [unilateral or bilateral], onset [gradual or acute], character [such as throbbing], radiation, association [any other signs], time course [duration], exacerbating/relieving factors and severity). Systemic issues such as flu should not be forgotten as these can be linked with the development of complications (Sankaridurg et al., 1996). It is important to enquire about possible precipitating/aggravating factors such as history of foreign-body insertion or trauma, photophobia, any eye itchiness or seasonal variation, or anyone in the family who has similar eye problems (e.g. transmission of viral conjunctivitis can occur from sharing towels). Differential diagnosis of reported pain or discomfort by eye-care practitioners is fairly comprehensive (Wolffsohn et al., 2015) and far superior to that found in pharmacy practice (although these studies used actual questioning of a mystery shopper; Bilkhu et al., 2013, 2014).

OCULAR HISTORY FOR THE PATIENT WHO IS OR HAS BEEN A CONTACT LENS WEARER

This includes:

- the last eye-test date and last contact lens aftercare
- brand / type of lens worn – note lens brand and care system recall is generally poor, but is much enhanced using photo-prompts (Dumbleton et al., 2011a)
- lens modality
- cleaning regimen (and ease of compliance) – risk factor for microbial keratitis (use of a multipurpose solution has a higher risk than hydrogen-peroxide-based solutions – Stapleton et al., 2012)
- the time since fitting (and why care is no longer being provided by the original lens fitter) or discontinuing (and what led to this)
- average daily wearing time (hours per day; days per week)
- comfortable wearing time
- any napping or overnight wear – extended/continuous wear are risk factors for corneal infiltrates and microbial keratitis (Morgan et al., 2005; Chalmers et al., 2012; Stapleton et al., 2012)
- the number of hours of wear at the time of consultation and how long it has been since the last aftercare – which help to determine the significance of any clinical signs seen during subsequent ocular examination such as corneal-solution-induced staining (Gorbert et al., 2014), as well as indicating likely future patient compliance.

OCULAR HISTORY FOR ALL PATIENTS

This includes:

- the last eye-test date
- any problems with their eyes such as discomfort/pain (if not already reported in the reasons for visit)
- any previous ocular surgery or trauma – such as laser refractive surgery that will affect corneal topography and sensitivity, as well as tear film stability (Nettune and Pflugfelder, 2010; Viso et al., 2011).
- previous ocular infections such as iritis or herpes simplex (Mucci et al., 2009)
- whether they have ever been to hospital / GP about their eyes
- any problems with their vision specifically at distance / intermediate / near
- pregnancy or lactation – due to hormonal changes, there is increased risk of corneal oedema and mucus build-up potentially affecting comfort (Gotovac et al., 2013).

MEDICAL HISTORY

This includes:

- general health
- any allergies (atopy) particularly if there is an ocular component (Wolffsohn et al., 2009)
- diabetes – this should not prevent successful soft contact lens wear, but requires more frequent monitoring owing to the potential for increased fragility of the epithelial tight junctions and decreased corneal sensitivity (O'Donnell et al., 2001) (See Chapter 34)
- thyroid problems – and other conditions that affect eyelid position or tone impacting the tear film (Pillar and Richa, 2014)
- system inflammatory conditions – such as sarcoidosis, which may be associated with ocular inflammation (uveitis; Weisinger et al., 2006)
- dermatological conditions – such as seborrheic dermatitis, atopic eczema and acne rosacea, all of which are strongly associated with anterior/posterior blepharitis (Auw-Haedrich and Reinhard, 2007).

MEDICATION

Information should be gathered as to any prescribed medication taken for systemic conditions (often not reported; Wolffsohn and Hurcomb, 2002) as well as topical ocular medication and self-medication (such as over-the-counter). Full reporting should include the dose and frequency as well as the pharmaceutical name. Asking patients to bring a list of their current medication saves valuable contact time with the patient and reduces the risk of inaccuracies (McKinley et al., 2004; Wolffsohn et al., 2015). There is little point in recording medication unless the potential effects on patient management are explored such as drug interactions and ocular side-effects. This is best achieved by using software, which can be more up to date than a practitioner's memory and aid patient recollection of pharmaceutical names. Preservatives in ocular medication are renowned for causing allergic reactions, which may explain the development of a red eye. Many systemic pharmaceuticals have dry eye listed as a possible complication, such as (Askeroglu et al., 2013):

- antihistamines
- nasal decongestants
- tranquilizers
- certain blood pressure medicines
- Parkinson's medications
- antidepressants
- birth control pills and hormone replacement therapy – although the evidence for these is contradictory (Brennan and Efron, 1989; Tomlinson et al., 2001).

FAMILY HISTORY

Taking a careful family history may identify that the patient has an as yet undiagnosed condition or one that may develop with ageing (hence record the age of onset and family relationship) such as:

- keratoconus – has a well-established genetic link, but a family history is not linked to severity (Szczotka-Flynn et al., 2008)
- myopia – has a generic link, but this does not influence progression (Bullimore et al., 2002)
- atopy (Buckley, 1998)
- corneal dystrophies (Delleman, 1978)
- dry eye (Henrich et al., 2014)
- diabetes – the type should be noted (Cahill, 1979).

SOCIAL HISTORY

Instead of asking about occupation and hobbies where responses such as 'retired' or 'student' explain little of the patient's visual demands and risks, questions such as 'What do you do during you working day?' and follow up with 'So what do you do when you are not at work?' may be more effective. Certain occupations and hobbies may require eye protection as well as contact lenses. The information documented should cover:

- occupation – higher socioeconomic status is a risk factor for microbial keratitis (Stapleton et al., 2012)
- visual tasks
- daily environment – although research is inconclusive about the effect of the environment on contact lenses (Papas et al., 2013), dusty environments and exposure to ultraviolet light should influence contact lens choice (Yam and Kwok, 2014)
- hobbies
- typical working distances
- computer screen use
- driving
- smoking – which is a risk factor for corneal infiltrates and microbial keratitis (Morgan et al., 2005; Chalmers et al., 2012; Stapleton et al., 2012).

Patient Education, Risk/Benefit Analysis and Informed Consent

It is important to get informed consent when fitting patients new to lenses as well as when patients are being refitted. Essentially this requires that the patient has a reasonable understanding of the main benefits of contact lens wear, as well as the potential risks that accompany lens wear.

Part of this process involves educating the patient on the various lens types and any that might be particularly suited (or unsuited) to the patient's particular needs. Information on wearing schedules and use of lenses in overnight wear, appropriate lens care systems and replacement intervals are all relevant factors in the patient's decision to proceed with lens fitting. Although there are many positive features to contact lenses, including visual, cosmetic and potentially psychological benefits, the patient must also be warned of possible adverse events.

As there are so many factors that might be relevant to the decision on contact lens wear, it is difficult to know how much information to provide. In general, it is not necessary to disclose every possible risk, but only those that a reasonable person or a member of the profession would expect to be told (Rosenwasser, 1991). Patients may need specific advice on aspects such as driving with monovision or where a particular undesirable outcome is not unexpected. Equally, it should be remembered that a minor can neither give informed consent nor contract to pay for services.

In some countries, it is common practice to ask the patient to sign a consent form, but the legal protection that this affords is questionable.

Patient Compliance

Encouraging compliance is a key element of any aftercare symptom and history taking. This topic is dealt with in detail in Chapter 42; however, a brief overview is provided here of some important compliance issues that may be discussed during history taking.

Non-compliance is common throughout the world (Morgan et al., 2011) and perceived compliance is not a good indicator of actual patient behaviours (Bui et al., 2010). Non-compliance has consequences that range in severity from reduced comfort on insertion and at the end of the day (Dumbleton et al., 2013), dryness and inferior vision (Dumbleton et al., 2010) to an increased risk of microbial keratitis from sleeping in lenses not prescribed for that purpose (Stapleton et al., 2008). Other physiological signs of non-compliance include deposition on the contact lenses (Collins and Carney, 1986a,b; Michaud and Giasson, 2002), corneal staining (Collins and Carney, 1986a,b; Nichols et al., 2002) and increases in papillae and hyperaemia (Michaud and Giasson, 2002; Cardona and Llovet, 2004). Risk-taking tendencies have been linked to compliance and, while not an easy direct question, they may become apparent from hobbies (Carnt et al., 2011).

The key aspects to emphasize are (Dumbleton et al., 2013):

- Failure to replace lenses when scheduled – reuse of daily disposable contact lenses is motivated largely by wanting to save money (60%) and occurs in □9% of patients (varying by country, from 18% in Australia, 12% in USA, 7% in UK to 4% in Norway). Over half of patients wearing fortnightly and monthly lenses have been found not to follow the manufacturer's or optometrist's replacement schedule recommendation (Dumbleton et al., 2011a; Hickson-Curran et al., 2011). In both these studies, failure to replace lenses when scheduled was linked with lower reported comfort on insertion and on lens removal (Dumbleton et al., 2011b, 2013).
- Sleeping in contact lenses – 75% of daily disposable contact lenses admit to napping in their lenses and 28% to

sleeping in them at least once a month. Sleeping in lenses at least once a week to a fortnight increases the relative risk of moderate to severe microbial keratitis (Stapleton et al., 2008, 2012).

- Inappropriate lens purchase and supply – internet purchase of lenses, rather than from a contact lens practice, appears to prevent patients from receiving the education, clinical care and follow-up required and has been shown to be associated with a greater risk of developing microbial keratitis (Stapleton et al., 2008, 2012).
- Use of tap water and failure to wash hands – generally patients report that they have been poorly instructed on the use of storage cases and tap water, and have a general lack of awareness with respect to hygiene such as handwashing (Dumbleton et al., 2013).
- Failure to clean and replace cases regularly – poor case hygiene has also been associated with a greater risk of microbial keratitis (Stapleton et al., 2008, 2012). The lens storage case is rarely cleaned (only 25% of patients clean every or most days), tap water is generally used (67%), the cap is left on by 76%, and the case was only dried open, face down as recommended in 10% of patients in the study by Wu et al. (2011a, 2011b). In a North American study, the case was replaced only monthly in 12% of patients (Dumbleton et al., 2013).
- Inappropriate use of care systems – infrequent use of care systems has been shown to be a risk factor for both microbial keratitis and sterile keratitis in daily wear users (Stapleton et al., 1993), as has failure to wash hands (Dart et al., 2008; Radford et al., 2009). Failure to rub and rinse lenses also carries a greater risk of developing microbial keratitis (Butcko et al., 2007) and leads to higher rates of signs and symptoms (Dumbleton et al., 2011b). In both the relatively recent outbreaks of Fusarium keratitis and Acanthamoeba keratitis, topping up, rather than the required complete replacement of solutions each day, was shown to be associated with a greater risk of infection (Chang et al., 2006; Joslin et al., 2007). Use of tap water to rinse is linked with higher rates of Gram-negative bacterial contamination (Tilia et al., 2014).
- Swimming or showering in contact lenses – swimming allows accumulation of microbial organisms on or in the lens, especially those made of first-generation silicone hydrogel materials, which increases the risk of Acanthamoeba infection (Choo et al., 2005; Beattie et al., 2006). The effect can be reduced by the use of swimming goggles (Wu et al., 2011c).

Verification of elements of compliance can be achieved by asking patients to describe or demonstrate lens cleaning, lens case cleaning and handwashing (Wolffsohn et al., 2015). Given the limited contact time with patients and partial patient oral retention (Court et al., 2008), comprehensive but concise written guidance should be provided to all patients (Wolffsohn et al., 2015) at every visit (Claydon and Efron, 1994; Efron, 1997). This has been found to be one of the few ways to improve compliance successfully (Tilian et al., 2014), along with prescribing of daily disposable contact lenses (Morgan et al., 2011).

Conclusion

The initial assessment and history taking form the cornerstone upon which all subsequent clinical decisions will be built. It is important that this aspect of patient care is conducted thoroughly and to the highest standards. Time spent on this initial stage of the patient assessment may prevent much wasted time later in the management of the patient, when clinical decisions have been made unadvisedly.

Sound and thorough record keeping will ensure both good continuity of care and a good defence in the event of patient complaint.

Access the complete references list online at http://www.expertconsult.com.

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36

Diagnostic Instruments

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Introduction

The purpose of this chapter is to review a number of the clinical instruments that are of utility in the preliminary examination and ongoing care of contact lens patients. The emphasis will be on the design and principles of operation, with some comments on clinical use. Further details on the application of these instruments in contact lens practice can be found in Chapter 37. The instruments discussed here form only a subset of the full range of instruments that should be available to eyecare practitioners for examining all aspects of ocular health and visual function. General ophthalmic instruments that are used frequently (e.g. refracting equipment, retinoscopes, ophthalmoscopes) and periodically (e.g. tonometers, visual field analysers, colour vision and binocular vision assessment apparatus) in the course of a contact lens examination will not be considered here.

Observation of the Eye

Perhaps the most fundamental procedure in a contact lens consultation is the examination of the anterior ocular structures. The standard technique for examining the eye in detail is slit-lamp biomicroscopy, which has been available to practitioners since the invention of contact lenses over a century ago. More recently, high-powered observation tools have become available that allow examination of the living cornea at a cellular level.

BURTON LAMP

A number of manufacturers make a special hand-held magnifying device for contact lens work. This device is usually referred to as a 'Burton lamp', after the company that manufactured the original version (Burton Manufacturing Co., USA). The Burton lamp is essentially a large magnifying lens of about +5.00 D housed in a broad frame, within which are mounted a combination of 4 W white light and ultraviolet light fluorescent tubes, each 11 cm long. The operator can switch between the two light sources for white light and fluorescein stain examinations. A key advantage of this instrument is that both eyes of the patient can be viewed simultaneously, facilitating interocular comparison, which can be particularly useful in the course of rigid contact lens fitting (Fig. 36.1).

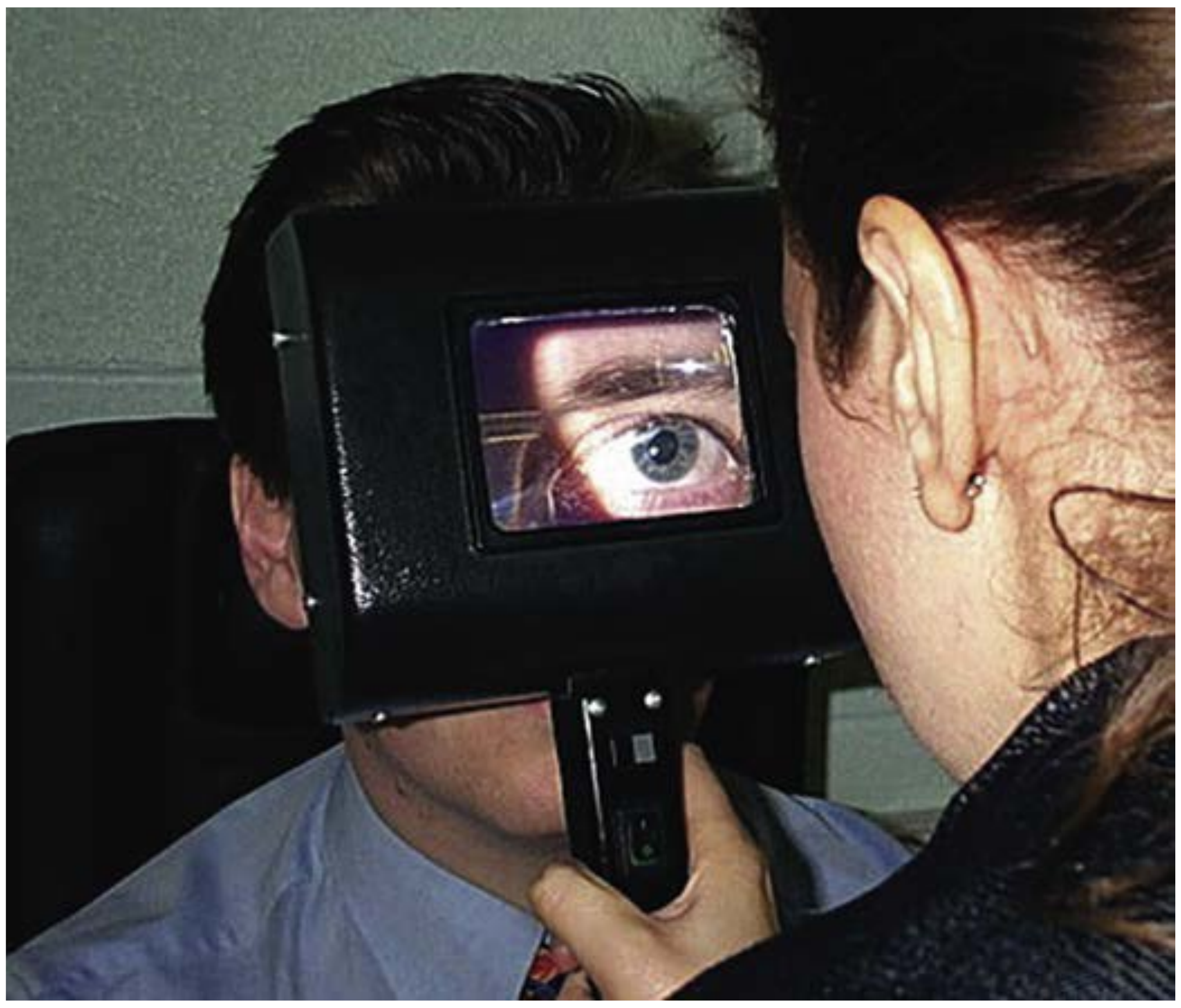


Fig. 36.1 Examining the eyes using a Burton lamp. (Courtesy of Philip Morgan.)

EXAMINATION OF THE TEAR FILM

A 'healthy' tear film is essential for successful contact lens wear, and a number of techniques are available for its assessment.

Tear Quality and Thickness

The Tearscope-plus (Keeler, UK) can be used to observe certain characteristics of the tear film non-invasively (Guillon, 1997) (Fig. 36.2A). This instrument takes the form of a small white dome with a central sight hole, surrounded by a cold light source. It can be held directly in front of the eye, or used in conjunction with a slit-lamp biomicroscope to gain higher magnification (Fig. 36.2B). The thickness distribution, quality and freedom of movement of the tears can be assessed by observing the reflected light from the featureless white dome, and the integrity of the aqueous and lipid phases can be inferred from colour fringe interference patterns (Guillon, 1998a, 1998b).

The Tearscope-plus has been discontinued and, although several are still in circulation, another instrument that can provide qualitative observation of the lipid layer is the OCULUS Keratograph®5M (Oculus, Wetzlar, Germany). The interference colours of the lipid layer and their structure are made visible using white light illumination and this pattern can be recorded. The thickness of the lipid layer is then assessed based on the structure and colour of this image, without using a dedicated interferometer.

The LipiView®interferometer was recently developed by TearScience®(Morrisville, NC, USA) to evaluate the tear film in patients with meibomian gland dysfunction (MGD) and dry eye (Blackie et al., 2009; Finis et al., 2013). This instrument (Fig. 36.3) uses interferometry to measure lipid layer thickness between blinks non-invasively, and gives a quantitative assessment in interferometric colour units. Partial blinks can be assessed, along with the change in lipid layer thickness and appearance. It is also of value to image the tear film before and after treatment of MGD and it can indicate the presence of

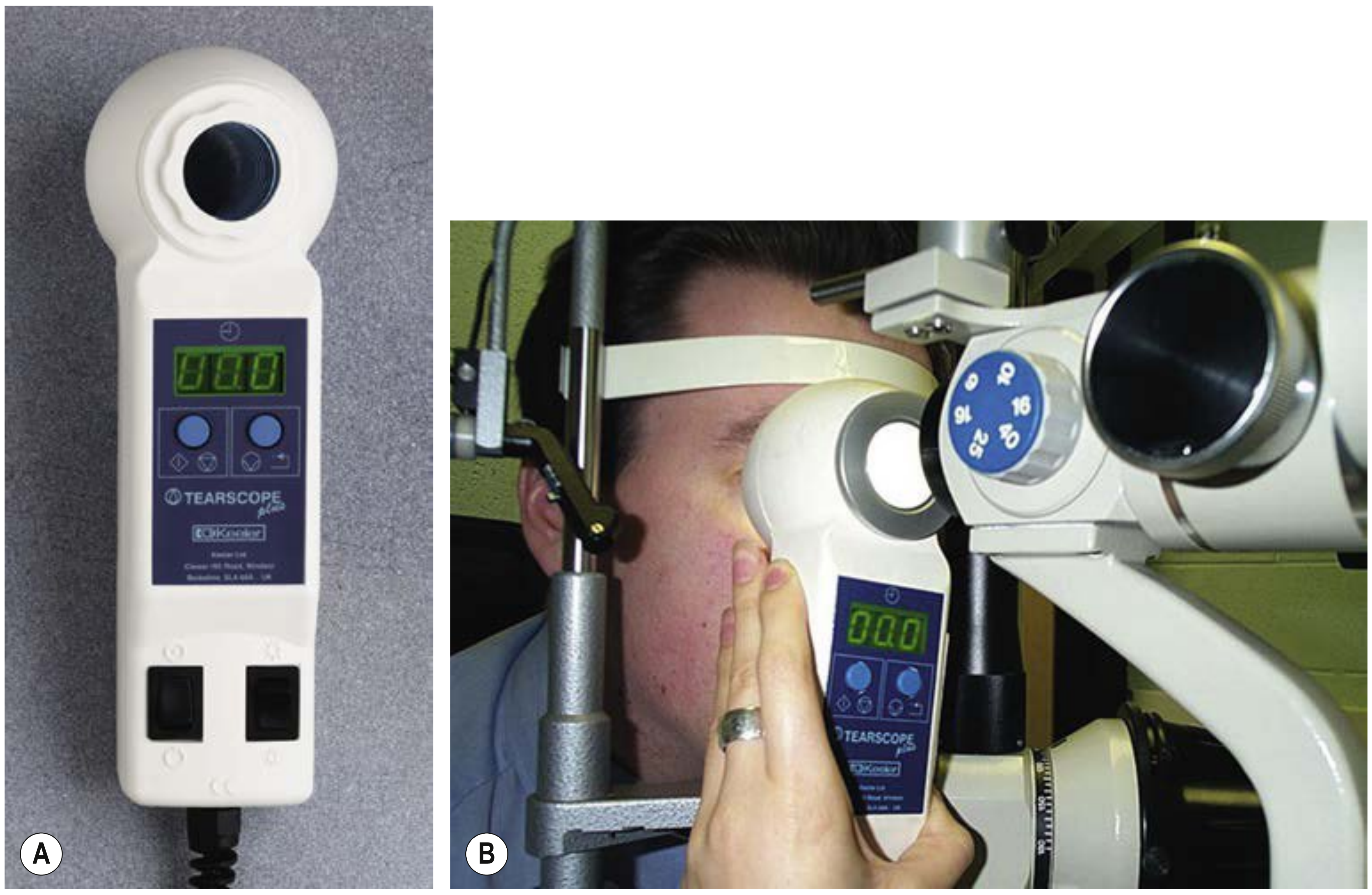


Fig. 36.2 (A) The Tearscope-plus. (B) Examining the eye with the Tearscope-plus in conjunction with a slit-lamp biomicroscope to obtain higher magnification. (Courtesy of Philip Morgan.)

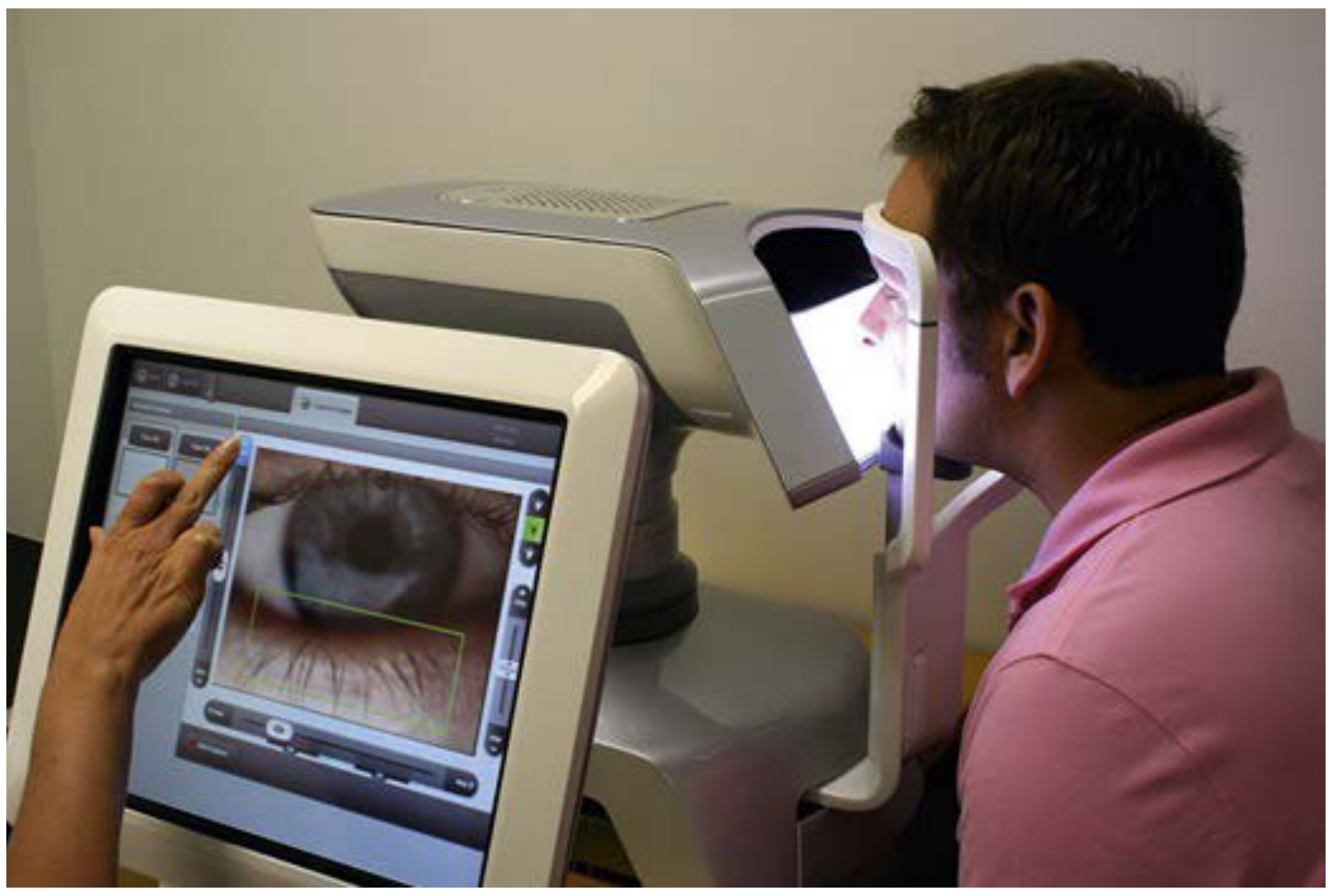


Fig. 36.3 TearScience LipiView interferometer in use. (Courtesy of Centre for Contact Lens Research and TearScience Inc.)

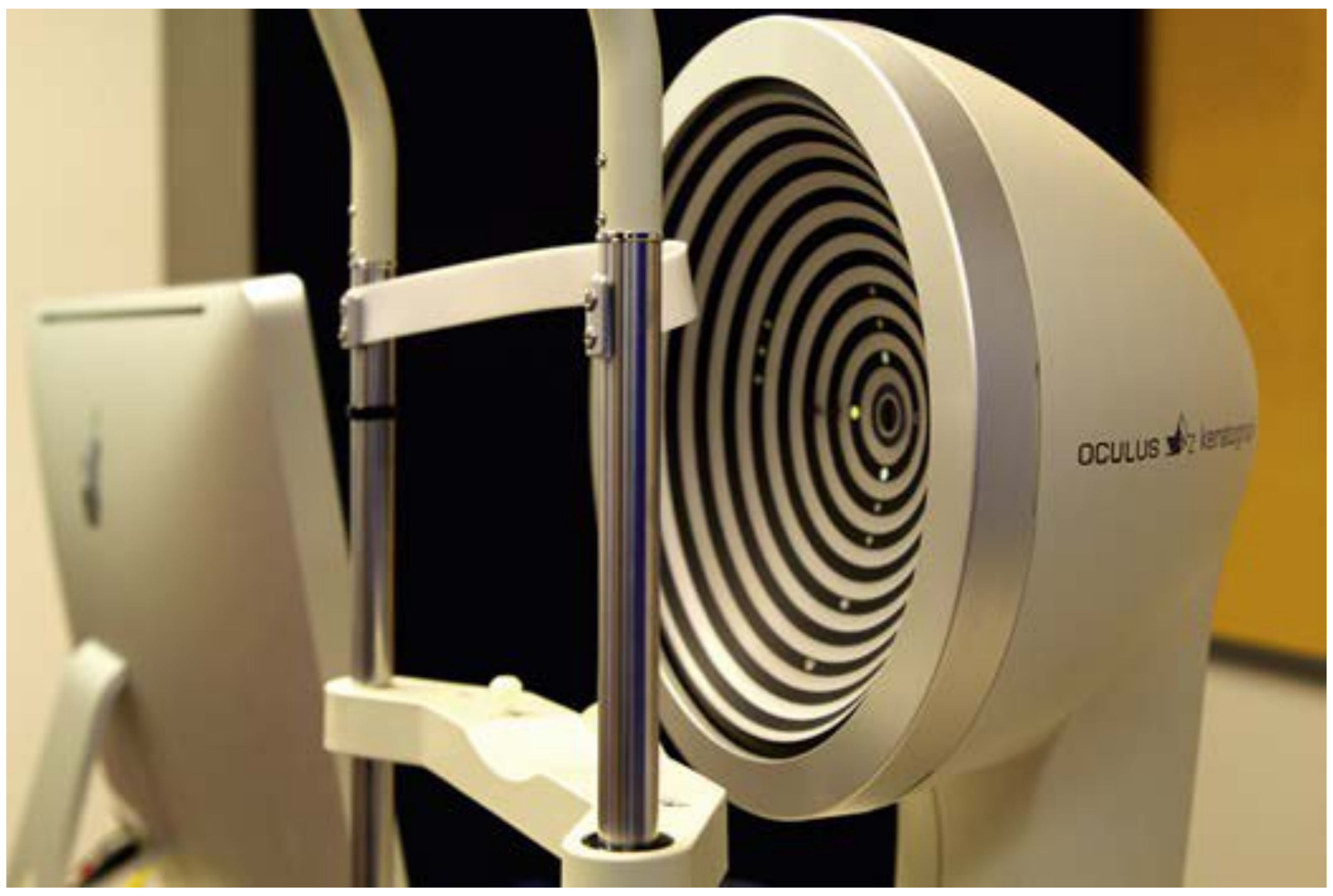


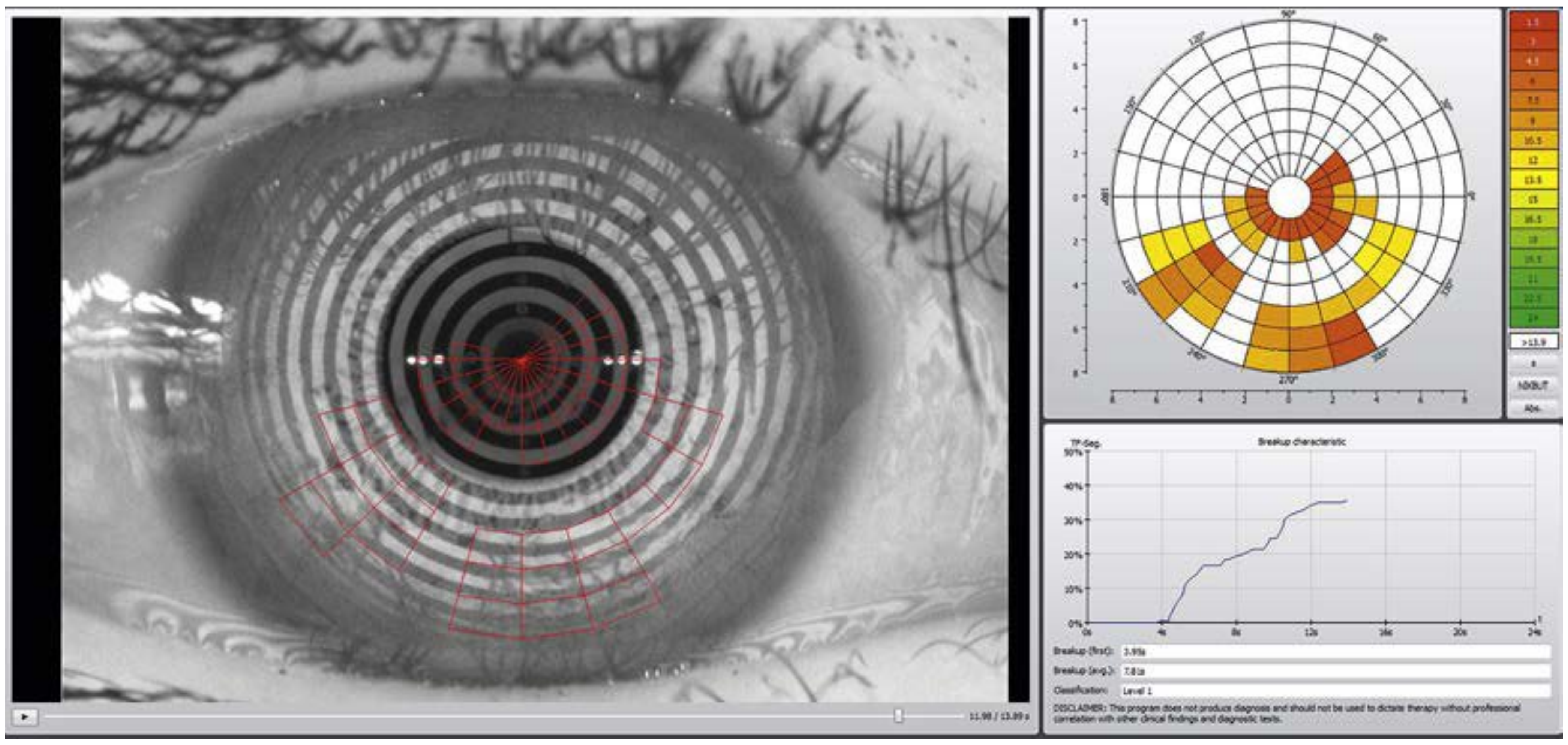
Fig. 36.4 OCULUS Keratograph 5M. (Courtesy of Centre for Contact Lens Research and Oculus.)

MGD (Finis et al., 2013), which could result in reduced comfort and potentially increased deposition in contact lens wearers.

Tear Break-up

Rapid tear break-up can lead to symptoms of dryness and discomfort in both lens wearers and non-lens wearers. Tear film break-up can be assessed by instilling fluorescein into the tear film and timing how long it takes for breaks in the even, fluorescent glow to appear. The problem with this fluorescein break-up time (FBUT) approach is that it is 'invasive', in that the instillation of fluorescein in itself alters the quality and quantity of the tear film (Mengher et al., 1985; Cho and Brown, 1993; Sweeney et al., 2013).

The preferred approach is to determine the non-invasive tear film break-up time (NIBUT). This can be achieved by optically projecting a grid pattern onto the cornea and timing how long it takes for the grid to become disrupted. Numerous 'specialist' devices employing this principle have been produced (Keir and Jones, 2013; Sweeney et al., 2013), including the instrument stand-mounted 'NIBUT dome' or 'Mengher grid' (Mengher et al., 1985) and hand-held devices such as the keratometer-mounted Hir-Cal grid (Hirji et al., 1989), the Loveridge grid (Loveridge, 1993) and the Tearscope-plus with NIBUT grid attachment (Guillon, 1997). One option to observe the tear film break-up without purchasing a dedicated device is to project the Placido rings from a corneal topographer onto the front surface of the cornea and manually count the seconds for the projected grid to distort (Srinivasan et al., 2008, 2010; Sweeney et al., 2013). Previous attempts have been made to automate this mire distortion (Goto et al., 2003, 2004; Kojima et al., 2004). More recently, the Keratograph 5M (Oculus; Fig. 36.4) has developed an automated tear film scanning process that allows automatic, examiner independent determination of tear film break-up time, providing a graphic representation referred to as a 'tear



Breakup (first): 3.95s
Breakup (avg.): 7.81s
Classification: Level 1
DISCLAIMER: This program does not produce diagnosis and should not be used to dictate therapy without professional correlation with other clinical findings and diagnostic tests.

Fig. 36.5 Tear break-up time as measured with the OCULUS Keratograph 5M. The heatmap on the right identifies the areas of tear break-up as auto-detected by the K5M. The colour-coding corresponds to the time until break-up, using a 'traffic-light-based' scale from very short (red) to very long (green). The associated sections of break-up on the recorded video (left panel) are shown by the red sections.

map', which shows the location of the tear break-up (Best et al., 2012; Hong et al., 2013, 2014; Lan et al., 2014). Colour coding indicates the regions of break-up: green indicates a stable tear film, yellow indicates a thinning tear film and red indicates tear film regions that are unstable (Fig. 36.5).

Osmometry

A clinical test that has been suggested as being highly diagnostic involves measuring tear film osmolarity (Tomlinson et al., 2006; Khanal et al., 2008). This is often considered a 'gold standard' in the evaluation of patients with dry eye (Farris et al., 1986; Farris, 1994; Tomlinson and Khanal, 2005), owing to the hypertonic tear film found in dry-eyed individuals (Gilbard et al., 1978, 1987, 1989; Farris et al., 1983; Lemp, 1995). A hypertonic tear film causes ocular surface damage and may lead to discomfort (Gilbard et al., 1978, 1987; Lemp, 1995). Even though tear osmolarity has been considered a valuable method for diagnosing dry-eye syndrome for several decades, until recently it has not been used widely as a clinical tool owing to the lack of available equipment and the fact that most osmometers require a large volume of tears (typically 5–10 µl) (White et al., 1993; Miller et al., 2003), which limits their use in many dry-eye subjects, particularly those with severe disease in which tear volume is very low.

Historically, measuring tear film osmolarity was undertaken using a freezing-point depression method (Tomlinson and Khanal, 2005; Stahl et al., 2012), most frequently using the Clifton instrument. However, this instrument requires considerable expertise, is time consuming and the equipment is difficult to maintain (Farris et al., 1986; Nelson and Wright, 1986; White et al., 1993). A new osmometer has recently become available that requires much less fluid (Sullivan, 2005; Versura and Campos, 2013; Yoon et al., 2014). This 'lab-on-a-chip'-based osmometer (TearLab: TearLab Corporation, San Diego, CA, USA) (Fig. 36.6) uses electrical impedance and requires only 50 nanolitres of tear fluid (Sullivan, 2005; Tomlinson et al., 2010; Jacobi et al., 2011; Versura and Campos, 2013). A test card is inserted into a 'pen-shaped' holder, which is gently placed in contact with the tear film for approximately 30 seconds. This is then placed into a portable countertop unit that calculates and displays the osmolarity test result. The reader automatically converts the tear fluid sample data into an osmolarity measurement and displays the reading on the LCD display. This rapid acquisition of osmolarity has resulted in an expansion of the utility of osmolarity determination in clinical practice (Tomlinson et al., 2010; Versura et al., 2010; Jacobi et al., 2011; Versura and Campos, 2013).

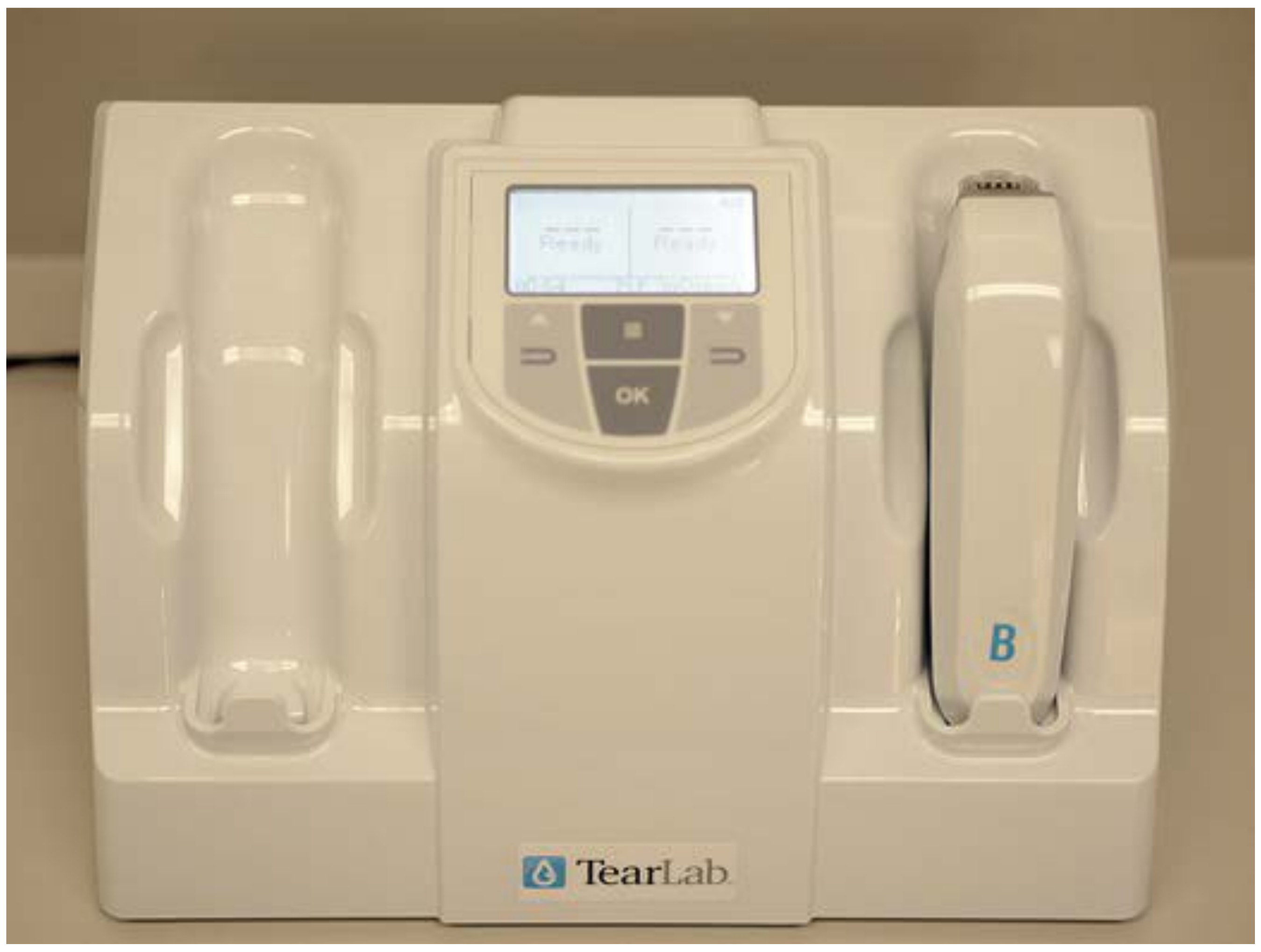


Fig. 36.6 TearLab osmometer showing the system pen that holds the test card and docking station (system reader) that provides the osmolarity readout. (Courtesy of Centre for Contact Lens Research and TearLab Corporation.)

Tear Meniscus Height

An adequate volume of tears is a prerequisite for a healthy ocular surface (Holly and Lemp, 1977; Miller et al., 2004) and a reduction in the volume of tears gives rise to a greater chance of symptoms of ocular dryness (Doughty et al., 2001). Estimation of tear volume is often undertaken using Schirmer strips (Lamberts et al., 1979; Yokoi et al., 2000), or phenol red threads (Tomlinson et al., 2001) or estimating the volume of tears in the inferior tear meniscus (Lim and Lee, 1991; Golding et al., 1997; Oguz et al., 2000; Patel and Wallace, 2006; Santodomingo-Rubido et al., 2006; Savini et al., 2006). The inferior tear meniscus contains about 90% of the tear volume (Holly, 1985) and tear meniscus volume is classically determined by estimating the tear meniscus height (TMH) (Patel and Blades, 2003; Patel and Wallace, 2006; Santodomingo-Rubido et al., 2006; Savini et al., 2006). Studies have shown that TMH estimation is a good clinical indicator in differentiating dry-eyed versus non-dry-eyed patients, as it is a direct measure of the quantity of the tear film (Lim and Lee, 1991; Mainstone et al., 1996; Golding et al., 1997; Pult et al., 2011; Altan-Yaycioglu et al., 2013; Tung et al., 2014).

The most common and simple method to determine TMH is visualizing the TMH using a slit-lamp biomicroscope with an eyepiece containing a graticule (Lamberts et al., 1979; Lim and Lee, 1991; Papas and Vajdic, 2000; Miller et al., 2004; Nichols et al., 2004; Patel and Wallace, 2006; Santodomingo-Rubido et al., 2006). However, estimation of the upper border of the TMH is difficult and several studies have achieved this by adding a small volume of fluorescein to the tears (Lamberts et al., 1979; Port and Asaria, 1990; Lim and Lee, 1991; Mainstone et al., 1996; Golding et al., 1997; Oguz et al., 2000; Tomlinson et al., 2001). Enhancing the visualization of the upper TMH border by the addition of fluorescein is clearly invasive and may interfere with the tear volume determined, resulting in an overestimation of the TMH.

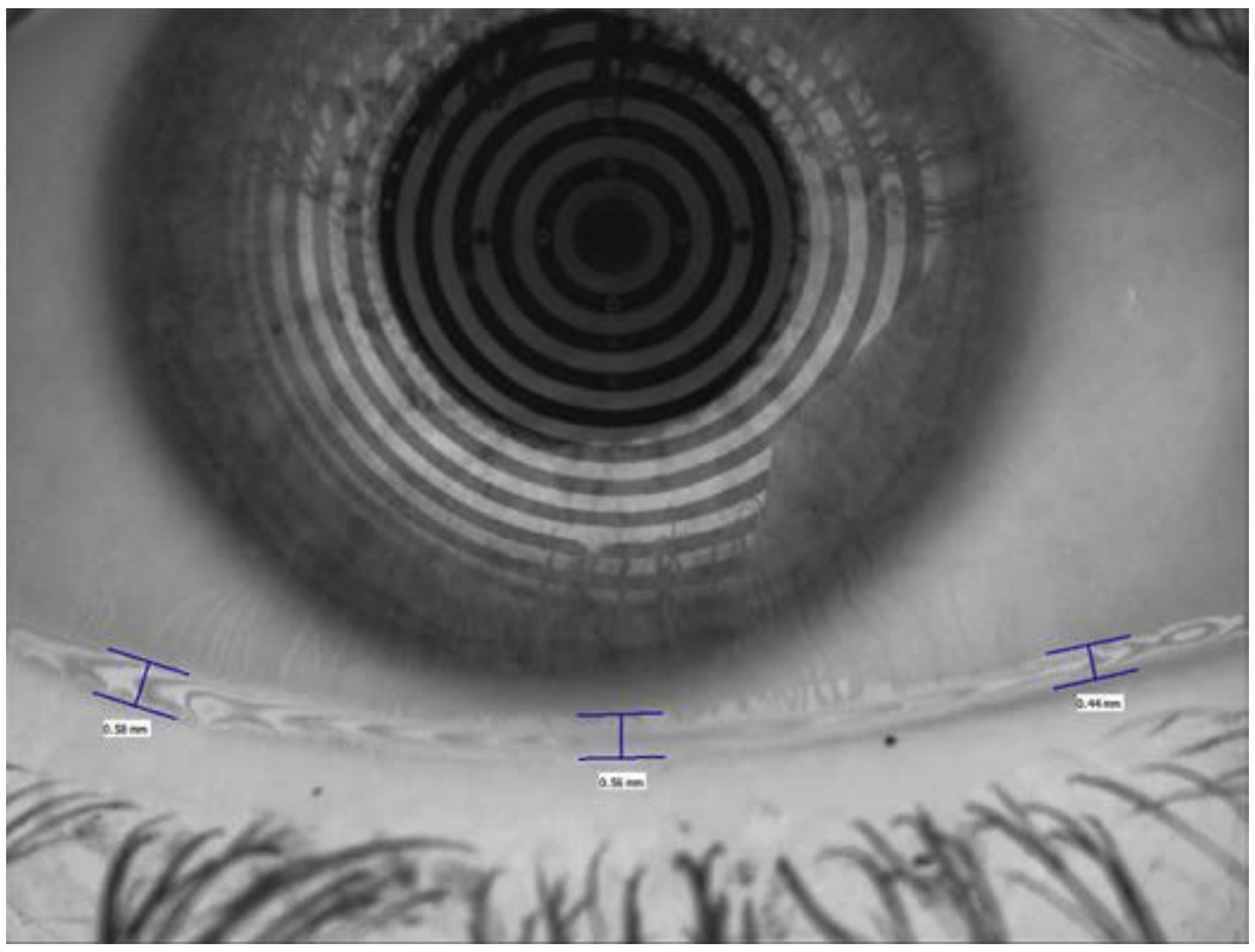
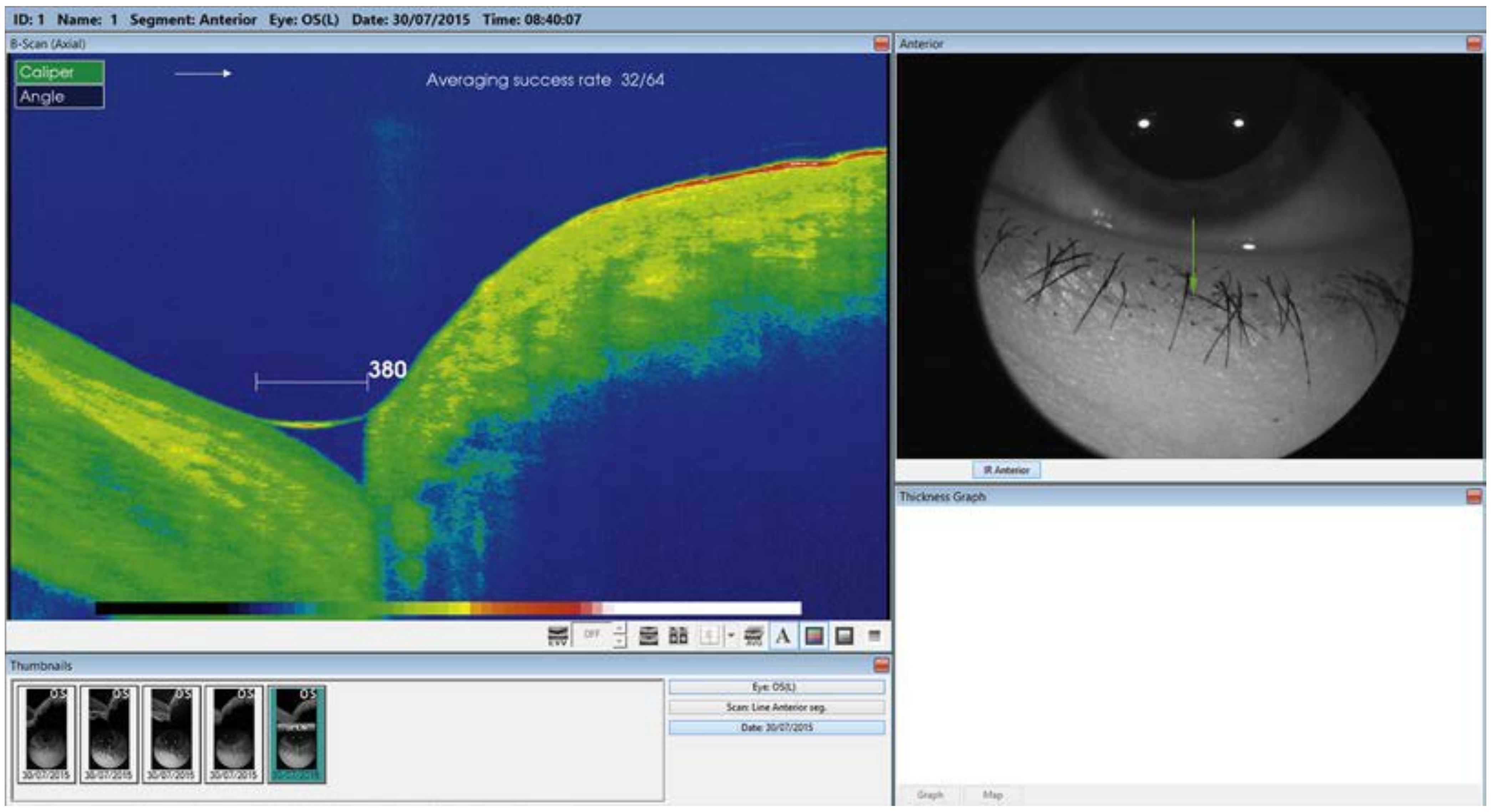


Fig. 36.7 Tear meniscus height (TMH) as measured with the OCULUS K5M. The ruler tool allows measurement of the TMH at any location along the lower lid margin. To facilitate viewing of the meniscus, the magnification of the acquired image can be adjusted.

To overcome such difficulties, a number of non-invasive approaches to measuring TMH have evolved, including videography of the meniscus (Golding et al., 1997; Oguz et al., 2000; Doughty et al., 2001, 2002), optical pachymetry (Port and Asaria, 1990; Patel and Port, 1991) and meniscometry (Francis et al., 2005; Stahl et al., 2006; Uchida et al., 2007; Bandlitz et al., 2014). Various multifunction devices now exist that can routinely photograph the TMH and include built-in software to determine the TMH. One of these, the OCULUS Keratograph® 5M (Oculus), photographs the lower TMH and its height can then be determined using a built-in ruler (Fig. 36.7) (Arriola-Villalobos et al., 2015; Koh et al., 2015).

Optical coherence tomography (OCT) has been used to determine TMH accurately (Jones et al., 2002; Johnson and Murphy, 2005; Savini et al., 2006; Wang et al., 2006a; Bitton et al., 2007; Keech et al., 2009; Shen et al., 2009; Ibrahim et al., 2010, 2012; Czajkowski et al., 2012; Ohtomo et al., 2014). Once the tear prism is visualized, images can be scanned and stored and the height within the OCT slice is calculated (Fig. 36.8). OCT offers an advantage in that it is the only available method to view the tear prism in cross-section to determine cross-sectional area (allowing for tear volume calculation) (Wang et al., 2006a, 2008; Palakuru et al., 2008; Chen et al., 2009, 2011; Garcia-Lazaro et al., 2012; Tung et al., 2014) and can also be used to determine the TMH of the upper lid (Wang et al., 2006a; Shen et al., 2009; Tao et al., 2010; Chen et al., 2011).



ID: 1 Name: 1 Segment: Anterior Eye: OS(L) Date: 30/07/2015 Time: 08:40:07

Averaging success rate 32/64

Eye: OS(L)
Scan: Line Anterior seg.
Date: 30/07/2015

Fig. 36.8 Optical coherence tomography (OCT) image of the lower-lid tear meniscus of a 24-year-old female showing the tear meniscus height. Image captured on the Topcon DRI OCT-1, which uses swept source technology. (Image courtesy of Nicholas Rumney.)

EXAMINATION OF THE MEIBOMIAN GLANDS

The various reports from the meibomian gland workshop conducted by the Tear Film and Ocular Surface Society clearly demonstrated the importance of having adequately functioning meibomian glands for ocular surface health and contact lens comfort (Nichols et al., 2011; Tomlinson et al., 2011). Evaluation of the meibomian glands has historically been obtained by practitioners merely pressing on the glands to view the expression of meibum. However, this is often difficult to do in a reproducible fashion. The Mastrota paddle (OcuSOFT, Rosenberg, TX, USA) (Fig. 36.9) is designed to gently and effectively express meibum from the meibomian glands (Pitts and Lievens, 2009; Hatley and Lighthizer, 2015). It is positioned between the eyelid and the eye, parallel to the glands, while a finger or cotton-tip applicator applies gentle pressure to the outer lid. This procedure can be carried out with or without anaesthesia. This tool is useful for the examination of meibomian glands and grading of meibomian gland function.

Although it is possible to evaluate correct functioning of the meibomian glands by applying digital pressure to the eyelid, the handheld Meibomian Gland Evaluator (TearScience) (Korb and Blackie, 2008, 2013) offers the advantage of standardizing this technique, regulating the consistency of pressure at 1.25 g/mm^2 (Fig. 36.10).

One of the most effective ways of evaluating the meibomian glands is to visualize and photograph their appearance using meibography (Yokoi et al., 2005; Pult and Nichols, 2012; Wise et al., 2012). This method, which is typically based on infrared illumination, is capable of assessing the number of partial glands or total meibomian gland drop-out (Jester et al., 1982; Mathers et al., 1991, 1994; Nichols et al., 2005). Although meibography has been conducted for many years in a research setting, a number of non-invasive, clinician-friendly devices have recently been released, making meibography possible as a routine procedure within clinical practice (Yokoi et al., 2005; Pult and Nichols, 2012; Pult and Riede-Pult, 2012; Srinivasan et al., 2012; Wise et al., 2012; Arita et al., 2013; Ban et al., 2013; Ngo et al., 2014). Two of these devices include the Keratograph 5M (Oculus) (Srinivasan et al., 2012; Finis et al., 2015; Ngo et al., 2014) (Fig. 36.11) and the recently released LipiView II with Dynamic Meibomian Imaging (TearScience).

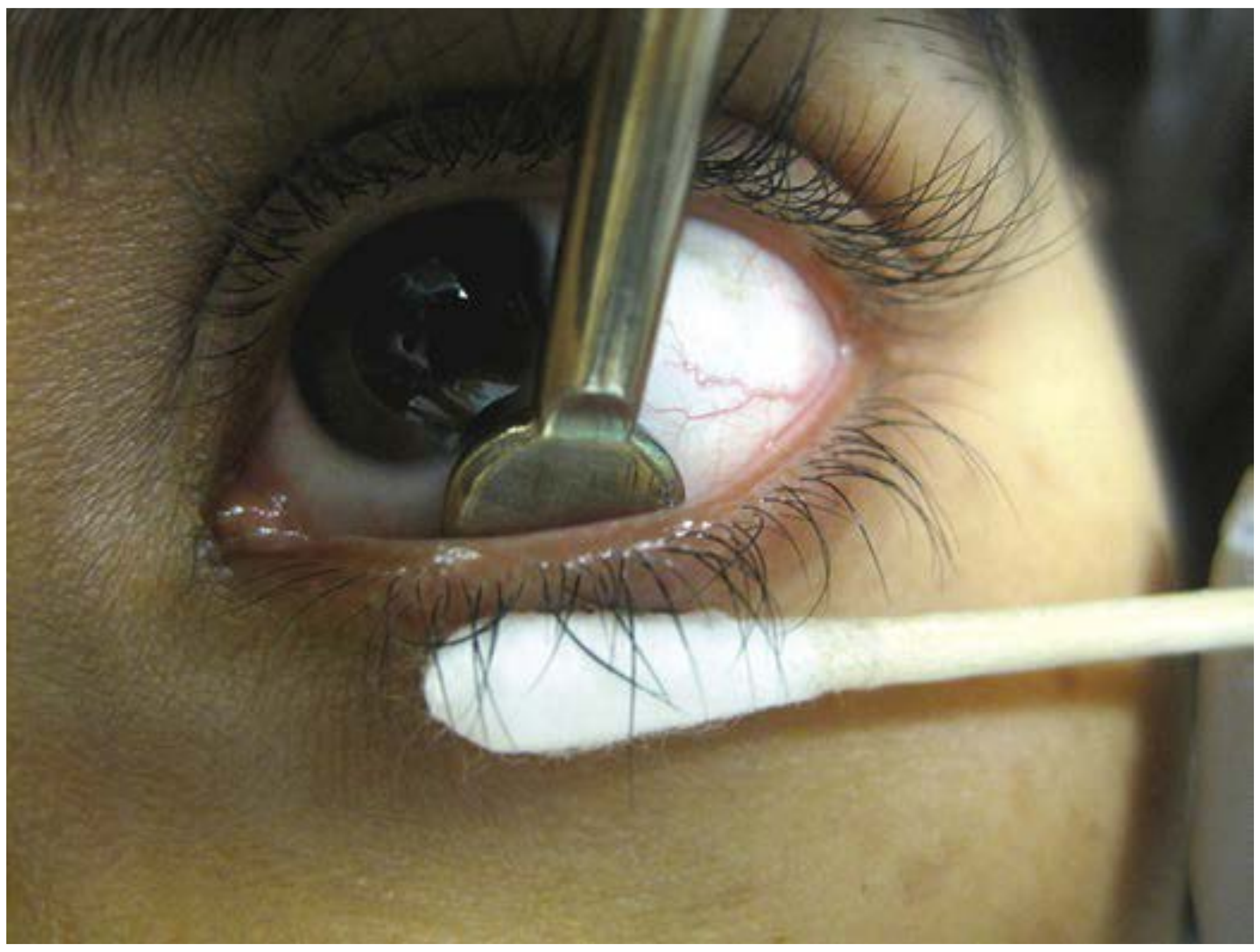


Fig. 36.9 Mastrota paddle being used to evaluate the functioning of the meibomian glands.

OBJECTIVE OCULAR REDNESS ASSESSMENTS

In clinical practice, ocular findings are typically assessed subjectively by means of image-based grading scales (Efron, 1998, 2012a; Papas, 2000; Efron et al., 2001b; Schulze et al., 2007; BHVI, 2011; Sickenberger, 2014). Despite the obvious convenience of their use, the inter- and intra-observer variability between repeated assessments has been open to criticism (Bailey et al., 1991; Papas, 2000; Fieguth and Simpson, 2002; Murphy et al., 2006; Schulze et al., 2008; Amparo et al., 2013). To overcome this limitation, various objective assessment methods have been proposed, including image analysis (Papas, 2000; Fieguth and Simpson, 2002; Schulze et al., 2008; Amparo et al., 2013) and photometric measurements (Schulze et al., 2007; Sorbara et al., 2007). Despite the advantages of these techniques, they are not easily achievable in clinical practice and remain largely used within research studies.

The Keratograph 5M (Oculus) uses modified optics to image the patient's cornea and also the visible nasal and temporal bulbar and limbal conjunctiva while the patient is looking straight ahead at the centre of the Placido disk rings (Jerchel et al., 2012; Oculus, 2013). The curved Keratograph head, with its concentric Placido disk rings, allows for consistent and uniform illumination across the visible conjunctiva (Jerchel et al., 2012; Wu et al., 2015). The built-in software automatically detects the visible nasal and temporal conjunctiva, and estimates redness by quantifying the area covered by vessels relative to the overall detected area (Jerchel et al., 2012; Wu et al., 2015). The Keratograph 5M output provides bulbar as well as limbal redness grades on a 0 (none) to 4 (severe) scale, in 0.1 increments, for both the nasal and temporal conjunctiva. In addition, an overall bulbar redness score based on a weighted average of nasal and temporal redness and the analysed area (in mm^2) are displayed (Fig. 36.12) (Oculus, 2013).

The Keratograph 5M allows a direct comparison of the acquired image to a published grading scale (the JENVIS 0–4 scale) (Sickenberger, 2014), which can help facilitate communication of the results with patients (Oculus, 2013). The hyperaemia results using this technology appear to be highly correlated to subjective grading (Jerchel et al., 2012), and have

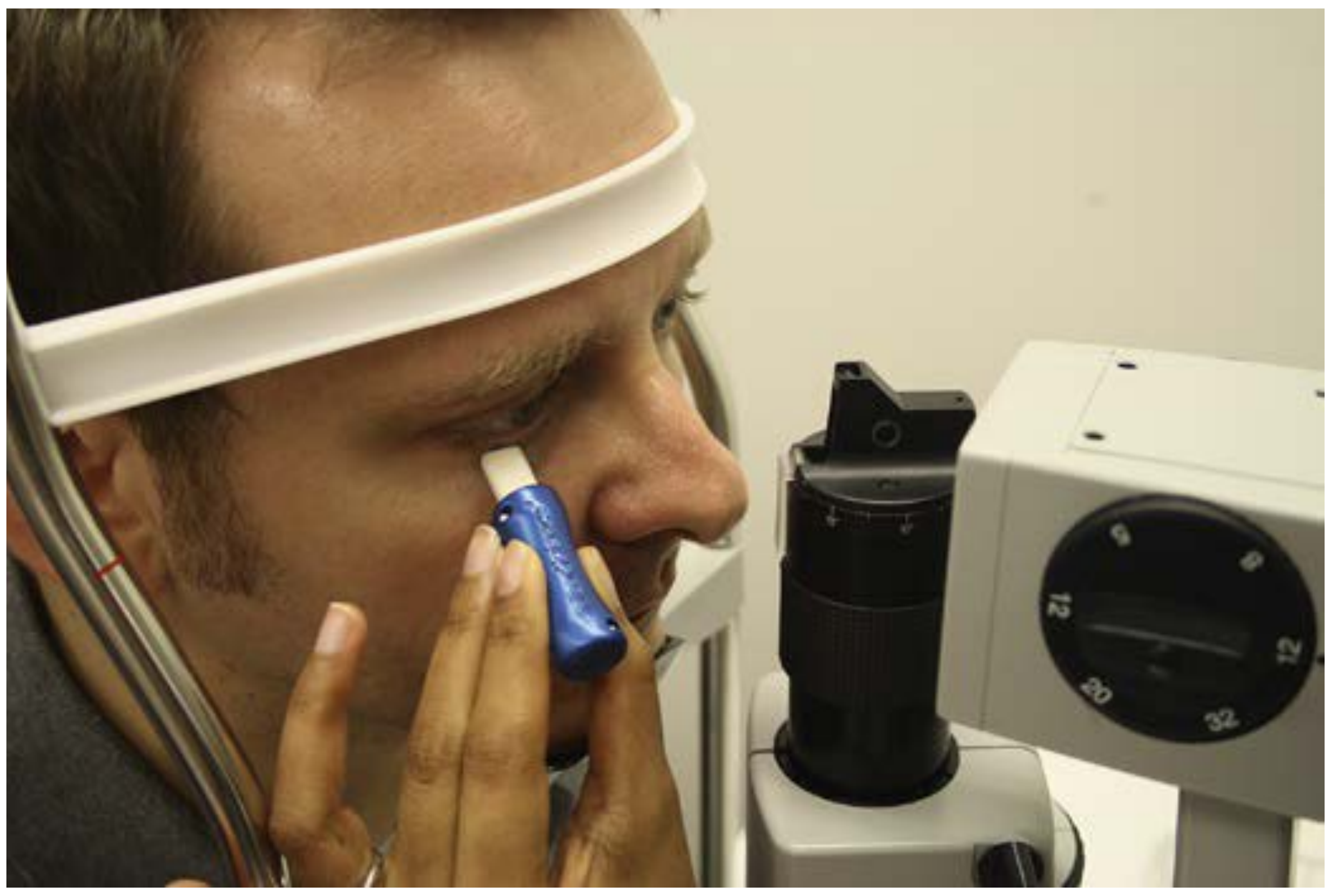


Fig. 36.10 Meibomian Gland Evaluator in use. This device applies a standardized pressure to the meibomian glands to evaluate their function. (Courtesy of Centre for Contact Lens Research and TearScience Inc.)

less variability than subjective assessments obtained by means of traditional grading scales (Jerchel et al., 2012; Wu et al., 2015).

SLIT-LAMP BIOMICROSCOPY

The slit-lamp biomicroscope plays an essential role in the preliminary assessment and aftercare of the prospective and existing contact lens wearer. The opportunities for using the slit lamp within the routine eye examination are numerous and diverse. With the appropriate application of supplementary lenses and / or viewing techniques, the instrument may be used to assess the condition of the vitreous, lens and retina from posterior pole to the ora serrata. Various ancillary instruments will permit examination of the anterior-chamber angle, measurement of intraocular pressure, corneal sensitivity and assessment of corneal thickness. This review will concentrate on the instrument itself: see Chapter 37 for an account of the use of the slit-lamp biomicroscope in contact lens practice.

The instrument consists of a separate illumination system (the slit lamp) and viewing system (the biomicroscope), which have a common focal point and centre of rotation (Fig. 36.13). A height control moves both systems simultaneously, whilst focusing and lateral movements are achieved via a joystick. This common control feature facilitates rapid and accurate positioning of the slit beam on the area of interest and ensures that the microscope and illumination system are simultaneously in focus.

Illumination System

Virtually all slit-lamp manufacturers have adopted the Koeller illumination system, which is optically almost identical to that of a 35 mm slide projector (Henson, 1996a). A bright illumination system (producing approximately 600 000 lux) is a fundamental requirement for a slit lamp if subtle conditions are

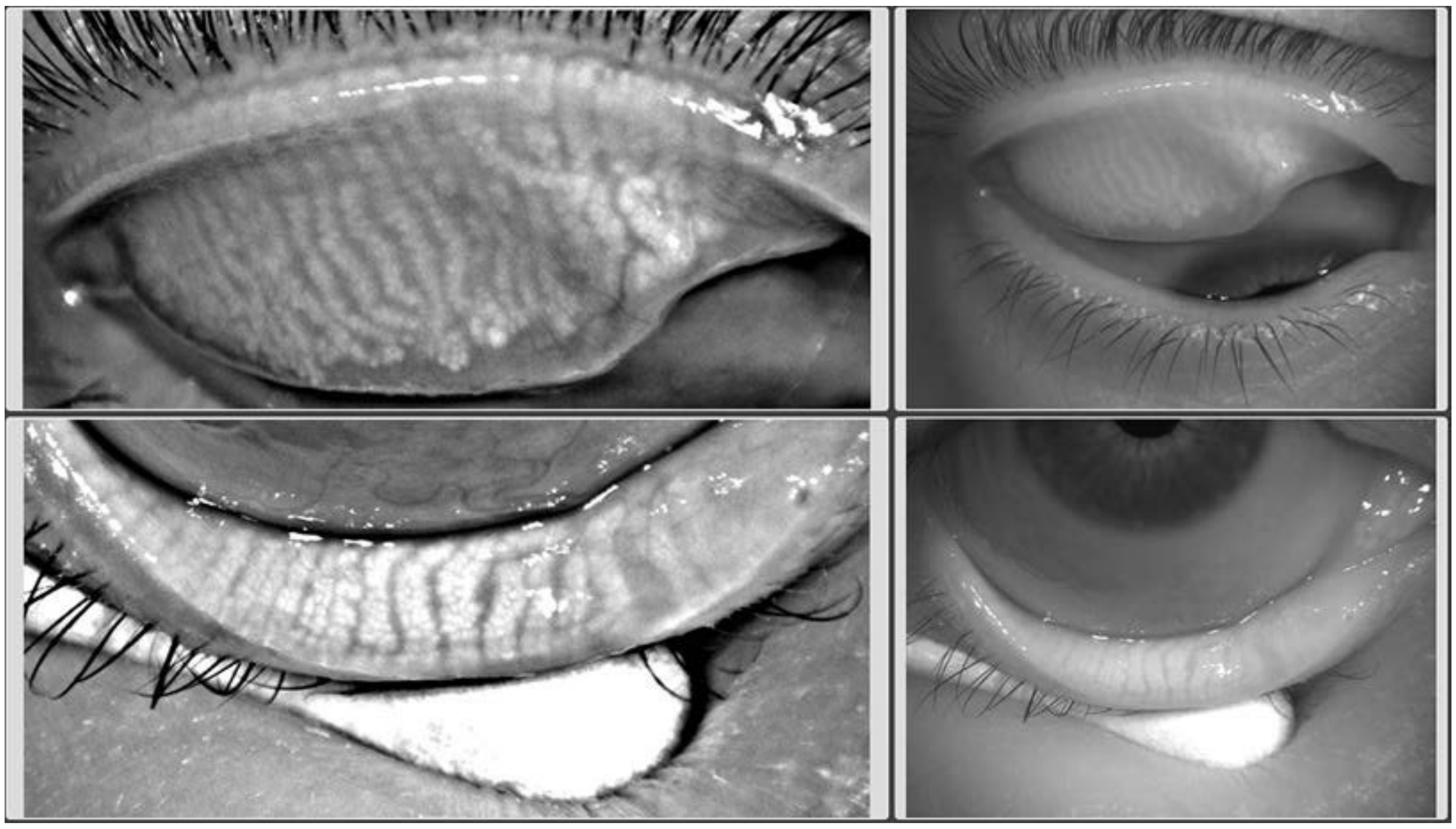
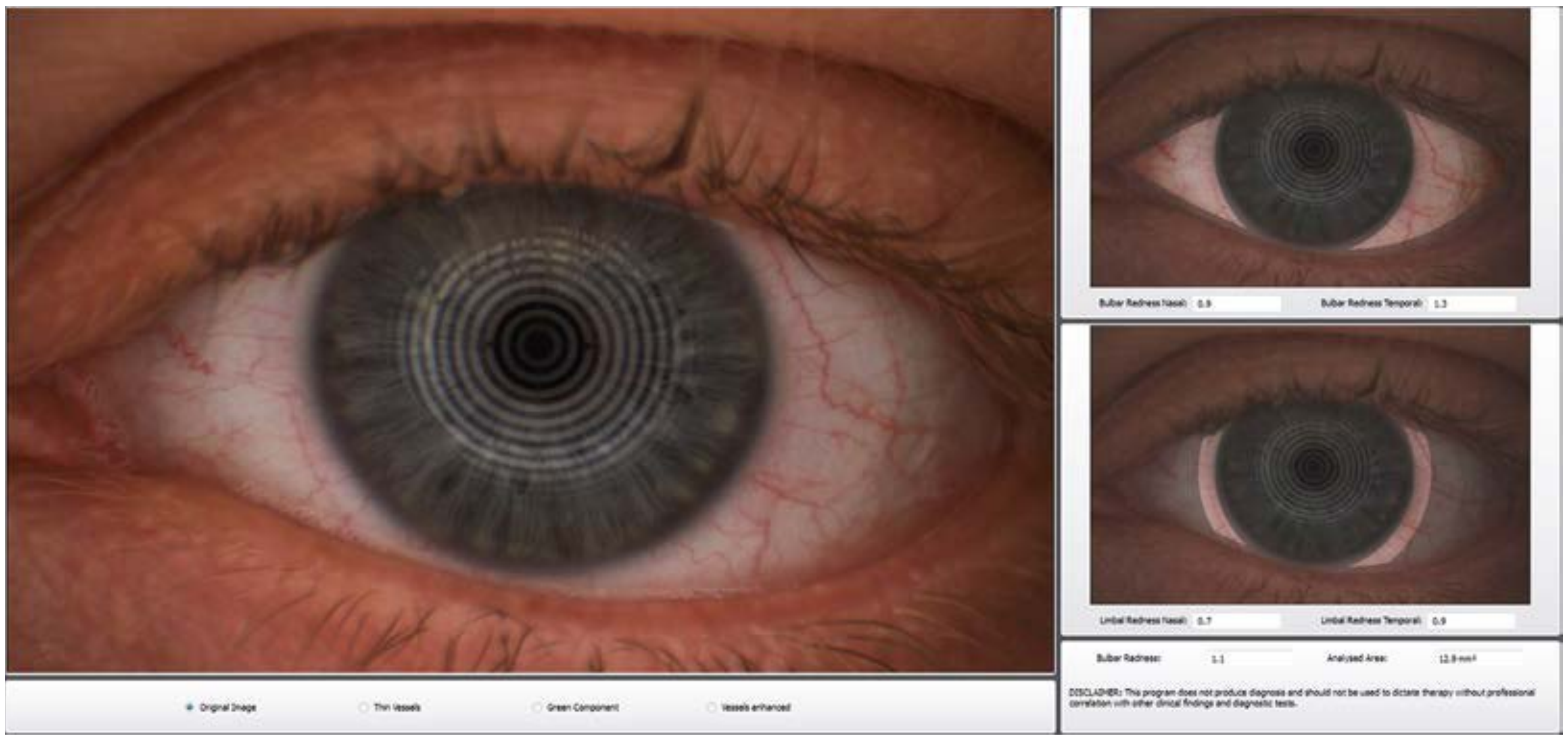


Fig. 36.11 Meibography of the upper (top panel) and lower (bottom panel) lid. On the right side of each panel are the original images as acquired with the Keratograph 5M, and on the left are enhanced versions of the same images to better visualize the glands.



Bulbar Redness Nasal: 0.9
Bulbar Redness Temporal: 1.3
Limbal Redness Nasal: 0.7
Limbal Redness Temporal: 0.9
Bulbar Redness: 1.1
Analysed Area: 12.9 mm²

DISCLAIMER: This program does not produce diagnosis and should not be used to dictate therapy without professional correlation with other clinical findings and diagnostic tests.

Fig. 36.12 Automated bulbar and limbal conjunctival redness obtained with the OCULUS Keratograph K5M. The data output includes grades (0–4 range; 0.1 increments) for nasal and temporal bulbar and limbal redness, as well as overall bulbar redness and the conjunctival area that was detected and analysed.

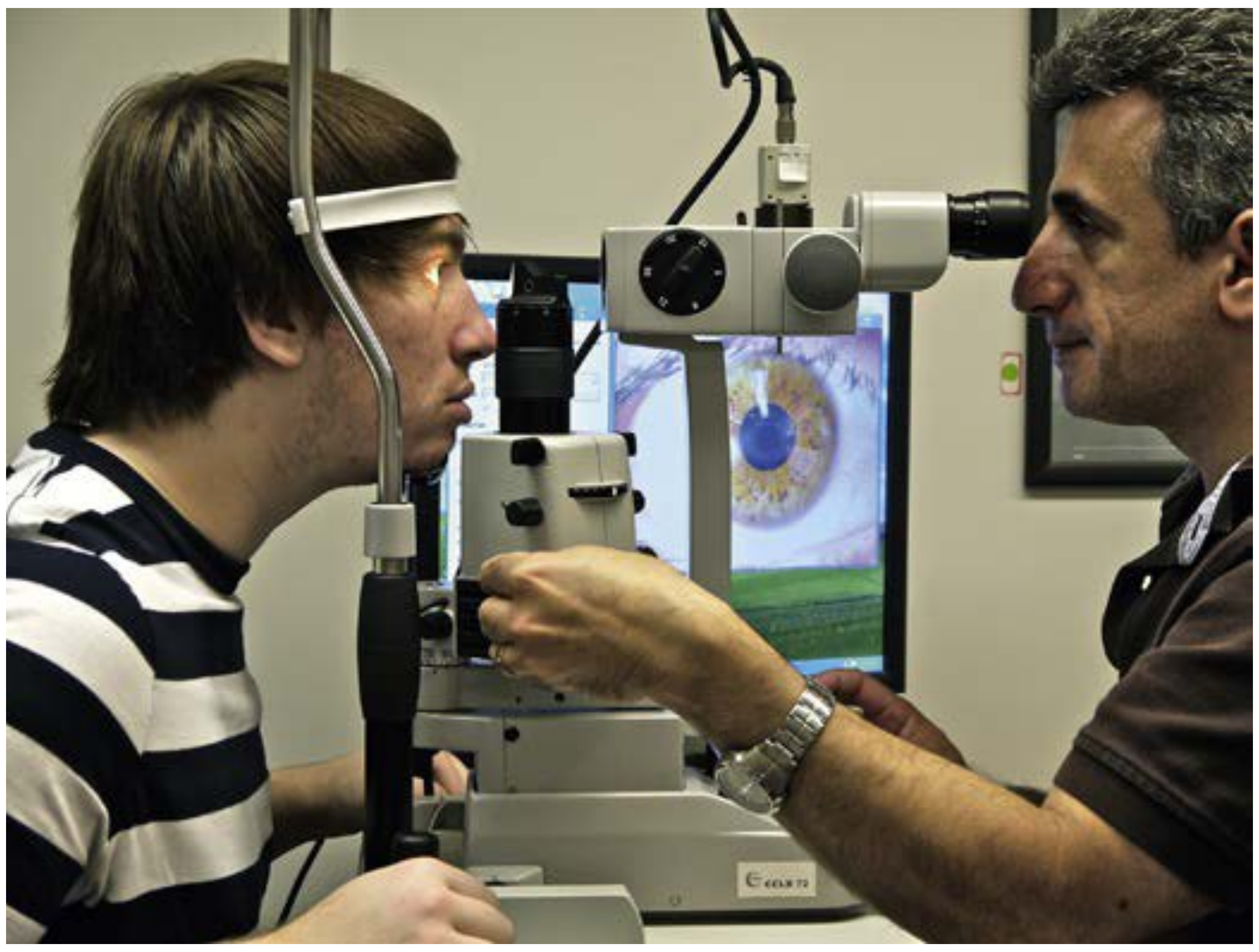


Fig. 36.13 The slit-lamp biomicroscope. Note the separate controls for the illumination system and the magnification system.

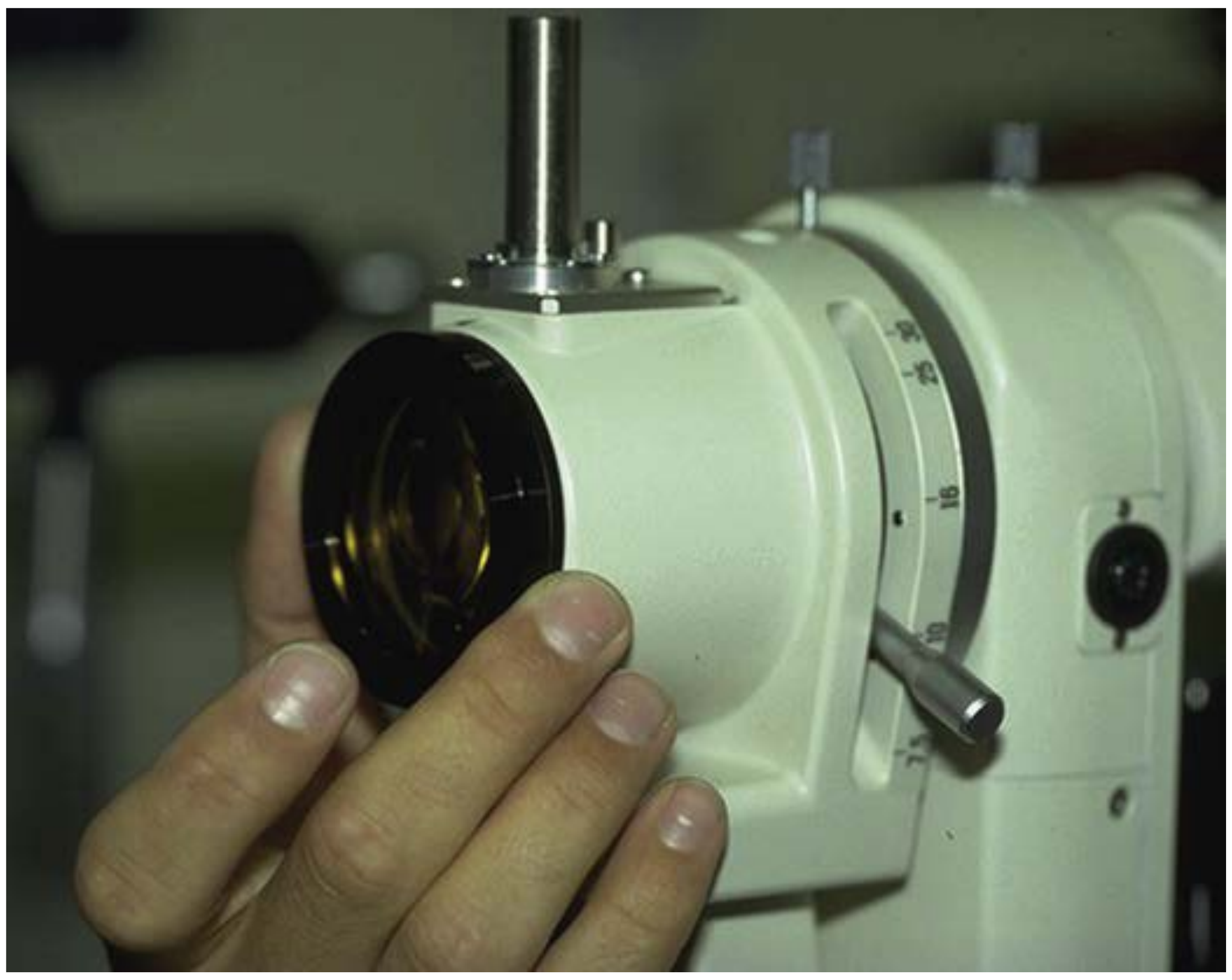


Fig. 36.14 Custom-designed barrier filter in position on the Nikon FS3 slit-lamp microscope. The slider for the zoom magnification system is also clearly seen.

to be seen clearly. Although halogen or xenon lamps are more expensive than tungsten lamps, they are the preferred illumination source as they provide a brighter light, last longer, have better colour rendering and generate less heat. Illumination brightness is controlled by a rheostat or multiposition switch such that brightness can be adjusted to obtain the correct balance between patient comfort and optimal visibility of the area of interest.

The slit within the illumination system must have sharply demarcated edges and desirable features include the following:

- The slit width and height must be easily adjustable such that any shaped patch from a slit to a circle may be projected, as this will increase the variety of illumination methods possible.
- A graduated slit width is particularly useful when measuring the size of a lesion.
- An ability to rotate the lamp housing such that the slit may be used in meridians away from the vertical is useful, particularly if a protractor scale is included. Such a system enables, for example, the angle of rotation of a soft toric lens away from the vertical to be accurately measured.
- The slit beam must have the facility to be displaced or offset sideways ('decoupled'). This ability to break the linkage between the illumination and observation systems facilitates indirect illumination techniques.

A number of filters can be incorporated into the illumination system; these serve to enhance the visibility of certain conditions:

- Green ('red-free') filter – enhances contrast when looking for corneal and iris vascularization, since red vessels appear black if viewed through such a filter. In addition, it may be used to increase the visibility of rose Bengal staining on both the cornea and conjunctiva.
- Neutral-density filter – reduces beam brightness and increases comfort for the patient.
- Polarizing filter – reduces unwanted specular reflections and can be useful to enhance the visibility of subtle defects.
- Diffusing filter – diffuses the illumination source over a wide area and is used to provide broad, unfocused illumination for low-magnification viewing of the general ocular surface.
- Cobalt blue filter – provides a suitable means of exciting sodium fluorescein for examination of ocular surface integrity. Illumination of fluorescein with cobalt blue light of 460–490 nm produces a greenish light of maximum emission 520 nm. Any abraded area will absorb fluorescein and display a fluorescent green area against a general blue background. The filter is occasionally used on its own to aid in the diagnosis of keratoconus. A frequent finding in this corneal ectasia is Fleischer's ring, which is formed by an annular iron deposition within the stroma at the base of the cone. The iron pigment is often difficult to see in white light, but will usually appear in greater contrast when viewed through the cobalt blue filter.
- Kodak Wratten number 12 (yellow) filter – this filter is not contained within the illumination system but rather is used as a supplementary barrier filter that is placed in front of the viewing system. It significantly enhances the contrast of any fluorescent staining observed with the cobalt blue filter as it allows transmission of the green fluorescent light but blocks the blue light reflected from the corneal surface (Back, 1988). Some newer slit lamps incorporate it within the viewing system, but for most practitioners it is used as an 'add-on' device that is placed over the observation lens when required. Custom-made barrier filters for certain slit lamps are available from some manufacturers (Fig. 36.14). Inexpensive hand-held versions may be constructed by using a cardboard mask and Lee filters number 101 yellow.

The Microscope

A key prerequisite for a slit-lamp biomicroscope is a viewing system that provides a clear image of the eye and has sufficient magnification for the practitioner to view all structures of interest. Magnification is an important consideration, and ideally magnifications of up to 40× should be possible; this may be achieved through interchangeable eyepieces and/or variable magnification of the slit-lamp objective (Henson, 1996a). More recently, the addition of digital cameras and subsequent image analysis has resulted in magnifications of up to 200× being possible (Yuan et al., 2015), allowing very fine details of the cornea and other external structures to be visible. Magnification greater than this level is usually unnecessary and is often counterproductive, as small involuntary eye movements will render the image too unstable to view. Ideally the practitioner should be able to change magnification swiftly and easily, which gives slit lamps with three or more objectives an advantage. Zoom systems have the added advantage of allowing the practitioner to focus on a particular structure without losing sight of it during changes in magnification. Of course, the magnified image must also be clear, and the importance of choosing a slit lamp with a high-quality optical system cannot be overemphasized. Ideally the microscope should have excellent resolution and a good depth of field. However, these factors are inversely linked and so a compromise must be accepted.

Mastering all of the possible illumination techniques with the slit lamp is essential if the instrument is to be used to its full potential. Practice with the instrument is critical to becoming comfortable with its subtle but extensive variety of uses. Readers are advised to consult other texts for information concerning the use of the many and varied illumination techniques available with the slit lamp (Zantos and Cox, 1994; Jones and Jones, 2000).

HIGH-POWERED MICROSCOPY

Conventional microscopy collects all the light reflected back through the object. As a result, information out of the focal plane, above and below areas of interest, creates noisy and blurred images in all but the thinnest specimens at high magnification (Cavanagh et al., 2000). Over the past 25 years two techniques (specular and confocal microscopy) have emerged that have enabled researchers and clinicians to examine the structure of the cornea in vivo at very high magnification.

Specular Microscopy

The specular microscope allows viewing of objects illuminated from above, and the objective lens also acts as the condenser lens. Light passes from inside the microscope out through the objective lens to arrive at a focus near the focal plane of the lens. If this position coincides with a reflecting surface then the focused light is reflected back through the objective lens and is viewed through the eyepiece of the microscope (Hodson and Sherrard, 1988). The first specular microscopes used for ophthalmic research were utilized by David Maurice in the 1960s in his work investigating corneal function. This technique enabled high-magnification images of both the epithelium and endothelium to be made, which had previously been difficult owing to their transparency. Early versions of the specular microscope used a contact dipping cone objective lens that was optically coupled to the cornea to provide higher magnification and resolution. However, most modern clinical specular microscopes can achieve equally high magnification without the need for ocular contact. These instruments are primarily used to view and photograph the corneal endothelium. The endothelial cells can be imaged because the refractive index of the endothelial cells is higher than that of the aqueous humour. By direct viewing with the specular microscope an overall impression of the condition of the endothelium can be established immediately.

Typically the features looked for are the regularity of the endothelial mosaic, the size of the individual cells, the presence of intracellular vacuoles and abnormal features such as corneal guttae and keratic precipitates (Rio-Cristobal and Martin, 2014). From the images obtained, factors such as the number of cells per unit area, cell shape and cell area can be calculated, enabling the clinician to assess the endothelial appearance compared with that expected of normal age-matched individuals. Results from these investigations (Hodson and Sherrard, 1988) have shown that the endothelial cell population density drops from approximately 4500 cells/m^2 at birth to 2000 cells/mm^2 in old age, and that their shape and size change dramatically over this time. At birth the endothelial mosaic is very regular and the cells are almost circular in shape. With time they become increasingly angular in shape and varied in size, a condition termed 'polymegethism' (see Chapter 40). In addition to age-related changes, the specular microscope has been used to investigate endothelial changes in a number of disease conditions, including posterior polymorphous dystrophy, Fuchs' dystrophy, corneal surgery, refractive surgery and contact lens wear (Hodson and Sherrard, 1988). In addition, deep stromal opacities such as glass foreign bodies, pigment deposits and corneal dystrophies can be imaged (Brooks et al., 1992).

Confocal Microscopy

Confocal microscopy is unlike conventional microscopy because defocus causes the image to disappear rather than appear as a blurred image. The properties of the confocal microscope stem from its ability to focus the illuminating light and the focal plane of the microscope objective on precisely the same point (Böhnke and Masters, 1999). In most modern confocal microscopes a point light source is focused on to a small volume within the specimen and a confocal point detector is used to collect the resulting signal. This results in a reduction of the amount of out-of-focus signal from above and below the focal plane, producing a marked increase in both lateral (x, y) and axial (z) resolution (Cavanagh et al., 2000). Only one tiny area of the specimen is observed by each point source, so a useful full field of view must be gained by mechanically scanning the area of interest. By varying the plane of focus of both the source and detector within the tissue, the specimen can be optically 'sectioned' non-invasively, and detailed information on corneal structure determined (Beuerman and Pedroza, 1996). Detailed descriptions of the optical principles involved in confocal microscopy can be obtained in various reviews (Böhnke and Masters, 1999; Cavanagh et al., 2000; Efron et al., 2001a).

The microscope objectives most commonly used are non-applanating water immersion objectives that are optically coupled to the cornea using a methylcellulose gel (Böhnke and Masters, 1999). To obtain the maximum axial resolution (and hence optical sectioning) it is necessary to use a microscope objective with a large numerical aperture (which describes the light-gathering ability of the objective). However, such devices have a reduced field of view and shorter free working distances, which reduces the distance that the microscope can focus into the specimen from the surface (Böhnke and Pedroza, 1999).

Tandem Scanning Confocal Microscopy. First-generation confocal microscopes used a modified Nipkow disc, which is a thin wafer with hundreds of pinholes that are arranged in a spiral pattern (Cavanagh et al., 2000). When a portion of the disc is placed in the internal light path of the confocal microscope, the spinning disc produces a scanning pattern of the subject. As the subject is inspected, light is reflected back through the microscope objective. The light that was reflected from in front of or behind the focal plane of the objective approaches the disc at an angle rather than perpendicularly. The pinholes of the disc permit only perpendicularly oriented rays of light to penetrate. This enables the microscope to view a very thin optical section of tissue. Because the illumination and detection of light through conjugate pinholes occur in tandem, this microscope was named the tandem scanning confocal microscope. The disadvantages of this system are a lack of a wide selection of objective lenses, an inability to control the signal-to-noise ratio directly at different tissue depths and the dramatic loss of light due to the fact that Nipkow discs transmit less than 1% of the available light (Cavanagh et al., 2000). This latter problem necessitates the use of a low-light-level camera to acquire the images, which limits frame speed acquisition.

Slit-scanning Confocal Microscopy. More recently, a variable-slit real-time scanning confocal microscope has been described (Masters et al., 1994). In this design, two independently adjustable slits are located in conjugate planes. A rapidly oscillating two-sided mirror is used to scan the image of the slit over the plane of the cornea to produce optical sectioning in real time. This design has the advantages of optimal image contrast, enhanced clarity and decreased scan time, but it is more expensive than Nipkow-based systems, and z-axis quantification is not currently possible (Cavanagh et al., 2000).

Confocal Microscopy through Focusing. Regardless of the technique used to obtain the images, the major problem associated with confocal microscopy relates to the interpretation and quantification of the data obtained. A relatively new technique called confocal microscopy through focusing attempts to overcome this, by rapidly moving the focal plane of the objective lens through the entire cornea at a speed of approximately 80 μm / s, while x–y images are acquired at the focal plane. This means that approximately 450 sequential images (which are separated by approximately 1 μm) are acquired over the time taken to traverse the cornea (approximately 15 seconds). The cornea is then reconstructed using image-processing techniques, and an image is produced that is similar to a histological section, albeit in three dimensions in a living cornea (Fig. 36.15).

Rostock Cornea Module. Heidelberg Engineering, in collaboration with Rostock University, Germany, has developed a novel digital confocal laser scanning microscope, a combination of Heidelberg retina tomograph (HRT) and the Rostock cornea module (RCM) (Stave et al., 2002; Zhivov et al., 2006; Patel and McGhee, 2007). The RCM uses the back-scattered light, similar to other confocal microscopes, with an interaction with the specimen producing a light signal that proceeds towards the detector. This device allows the operator to image cellular structures sharply and move through the different layers of the entire cornea, from epithelium to the endothelium. The RCM also enables the imaging of the peripheral areas of the cornea and conjunctiva. The instrument allows a scan depth of a maximum of 1500 μm, with an image size of 400 × 400 μm. The unit has an interchangeable 63× standard microscopic lens, offers a choice of manual depth position adjustment and has an automatic brightness adjustment system. The CCD camera allows a permanent monitoring of the corneal contact on the screen. The RCM technology provides better image quality and produces a precise depth measurement compared with confocal slit-scanning microscopes (Eckard et al., 2006) Recently, a more compact version of the same instrument, the HRT III with Rostock cornea module, has been introduced (Fig. 36.16).

Using such techniques, confocal microscopy has provided valuable data on the structure and appearance of the cornea in many disease processes, including dystrophies, keratitis and endothelial disease. In addition, corneal changes following refractive surgery, corneal cross-linking, keratoplasty, in diabetes and due to contact lens wear have been documented (Moller-Pedersen et al., 1997; Böhnke and Masters, 1999; Cavanagh et al., 2000; Efron, 2007, 2011, 2012b; Caporossi et al., 2012).

Measurement of Corneal Sensitivity

The cornea is richly innervated and is one of the most sensitive tissues in the body. Corneal sensitivity is a useful indicator of corneal disease and can help to determine physiological stress from wearing contact lenses (Brennan and Bruce, 1991; Millodot, 1994). Interest in assessing corneal sensitivity has increased over recent years, particularly in light of findings indicating that corneal sensitivity is significantly reduced in cases of dry eye and ocular surface disease (Xu et al., 1996; Adatia et al., 2004; Gallar et al., 2009; Achtsidis et al., 2013).

CONTACT AESTHESIOMETRY

Measurement of corneal sensitivity in the clinical setting has traditionally been achieved using a Cochet–Bonnet aesthesiometer (Fig. 36.17). This device can be hand held or mounted on a slit lamp, and uses a single nylon thread to produce various forces, by varying its length in 0.5 cm steps (the longer the thread, the lighter is the force). The filament is lightly placed on to the cornea by the clinician using a support that allows manipulation in the x–y–z planes, whilst the cornea is being viewed through the slit lamp. The subject reports when they can feel the thread touching the ocular surface, and the length of thread at which this occurs is recorded. The corneal touch threshold is defined as the length of the nylon filament at which the subject responds to 50% of the number of stimulations. This length is converted into pressure using a calibration curve and the reciprocal of this value gives the corneal sensitivity. Using this technique, it has been demonstrated that corneal sensitivity varies with surface location and is altered by age, iris colour, ambient temperature, time of day, contact lens wear and pregnancy (Millodot, 1994).

A number of factors complicate the use of such a device and can result in variations in the results obtained (Murphy et al., 1998). These include physical aversion to the approach of the device, problems with mounting the device accurately in the slit lamp and the impact of ambient humidity on the stiffness of the thread (Brennan and Bruce, 1991).

NON-CONTACT AESTHESIOMETRY

Over the last 15 years a number of devices have been tested and developed to overcome the problems described above with contact aesthesiometry. All of these research instruments use non-contact means of stimulating the cornea. Initially, mechanical stimulation alone was investigated, but more recently aesthesiometers have been produced that stimulate the cornea using a variety of thermal, chemical or mechanical stimuli. These have included non-contact pneumatic devices that deliver

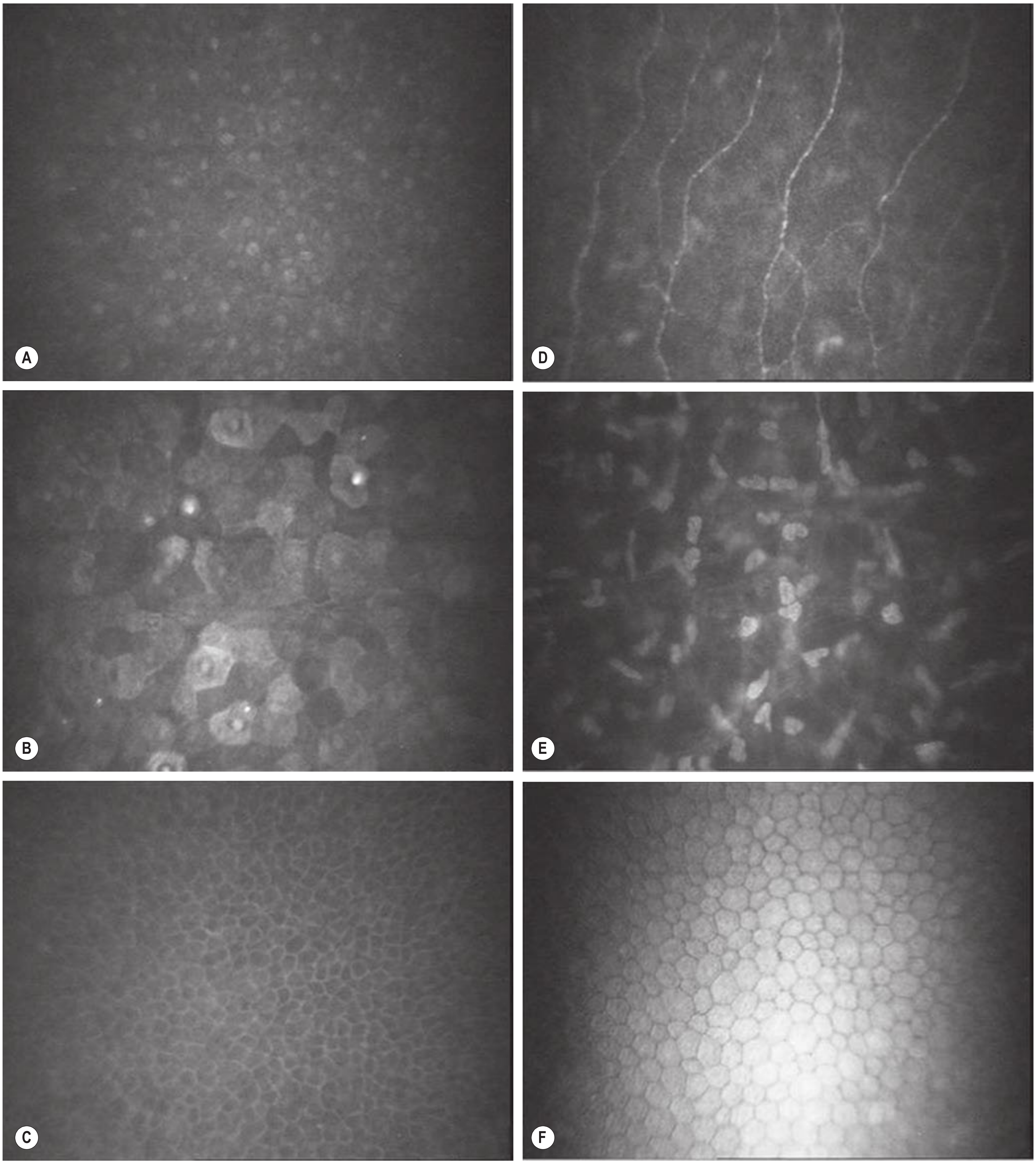


Fig. 36.15 Confocal microscope images of the corneal layers of a normal eye of a human patient. (A) Superficial epithelium; (B) intermediate epithelium; (C) basal epithelium; (D) subbasal nerve fibre layer; (E) stroma; (F) endothelium.

compressed air as the stimulus (Murphy et al., 1998; Vega et al., 1999) and a device that measures both mechanical stimulation via an air puf and chemical stimulation via the administration of varying concentrations of carbon dioxide (Belmonte et al., 1999; Gallar et al., 2004; Situ et al., 2007, 2008, 2010; Golebiowski et al., 2008, 2011, 2013; Basuthkar Sundar Rao and Simpson, 2014).

With time, it is possible that devices based on these approaches will become commercially available, and aesthesiometry will become an important technique in contact lens practice.

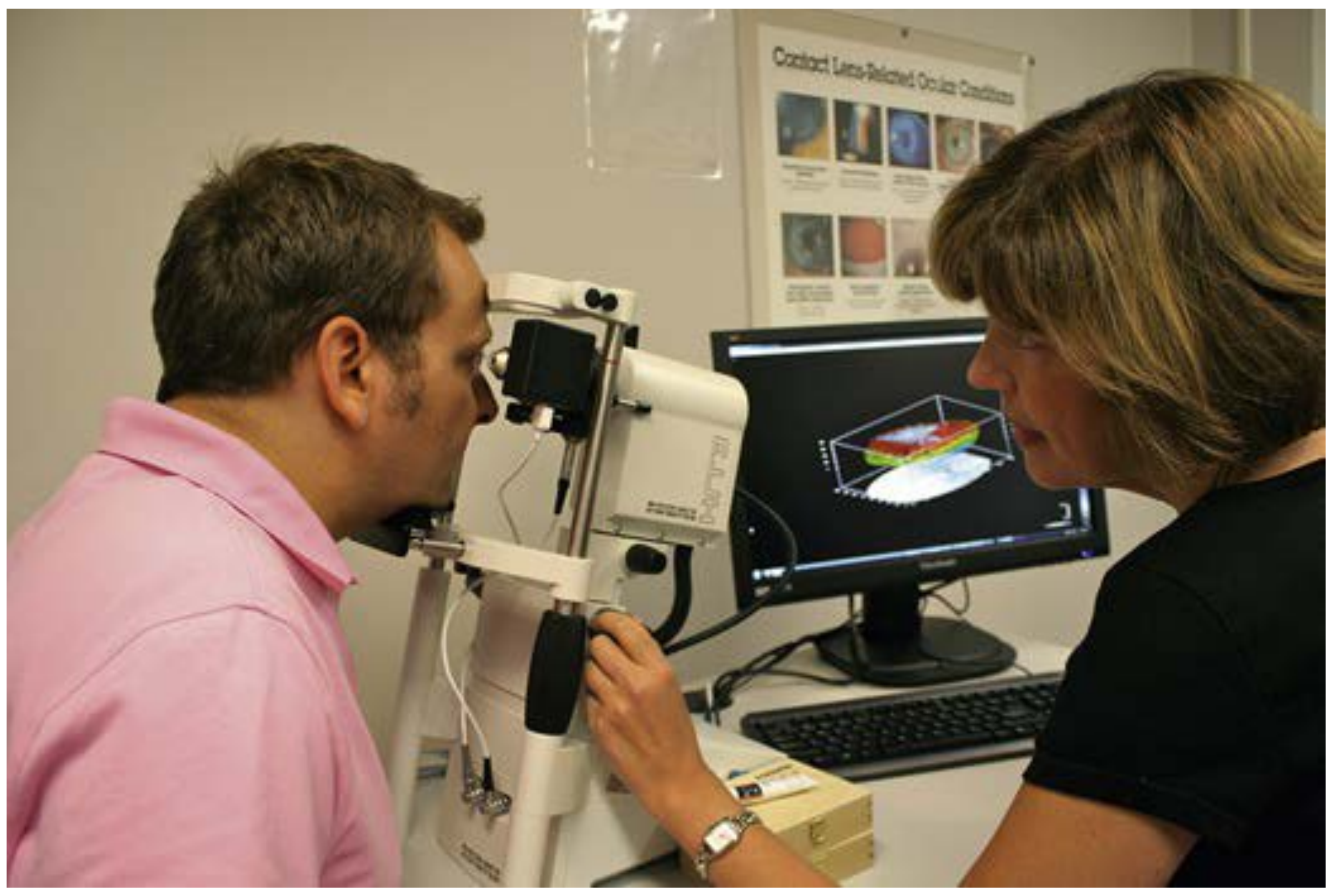


Fig. 36.16 The HRT III confocal laser scanning microscope.

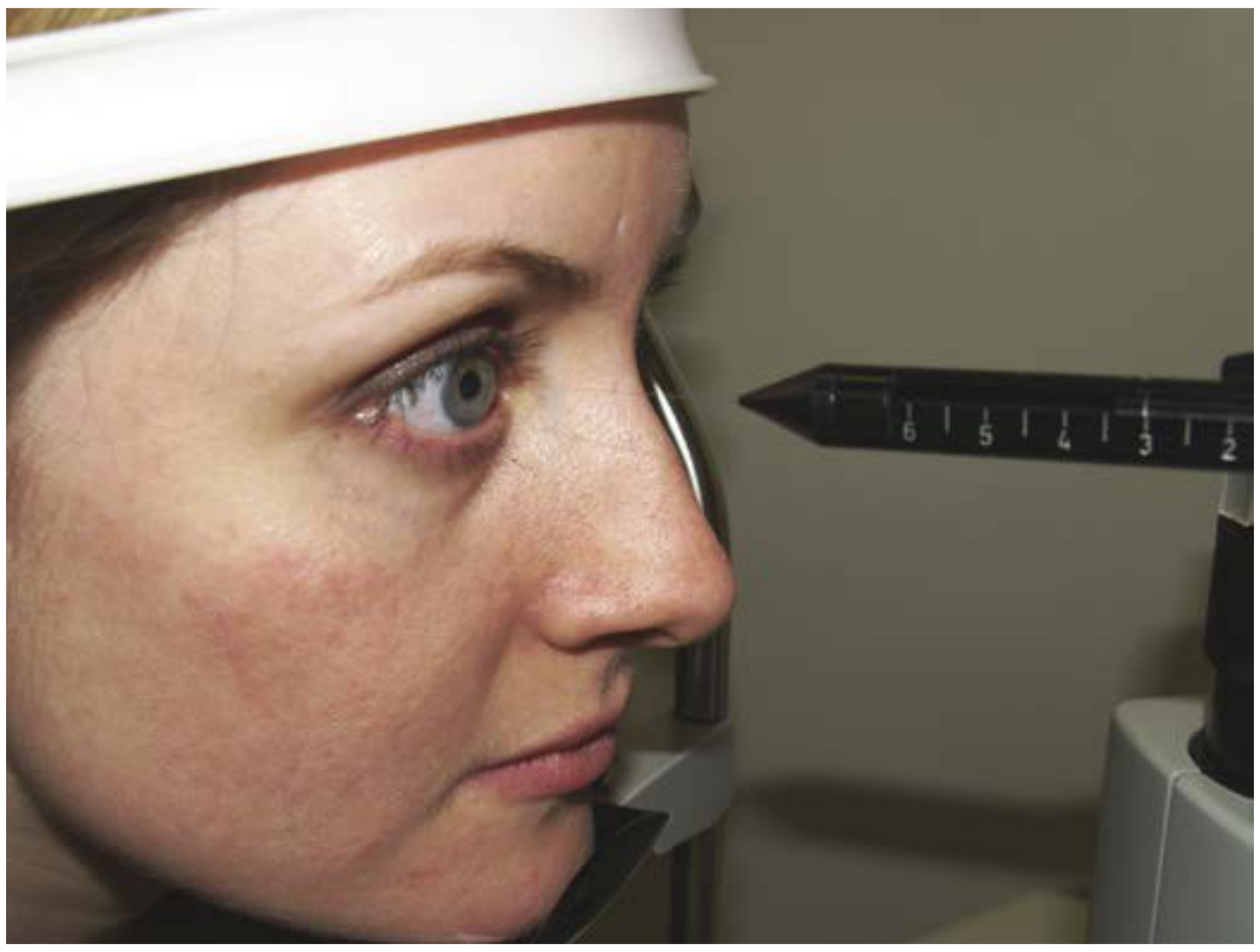


Fig. 36.17 The Cochet–Bonnet aesthesiometer being used to measure corneal sensitivity. A fine nylon thread of a set length is advanced towards the eye and the patient is asked to report when they first feel the thread touching the corneal surface.

Assessment of Anterior-segment Morphology

'Morphology' stems from Greek and relates to the 'study of shape'. Over the past two decades, improvements in computing technology has resulted in an explosion of the number of devices to determine the morphology of the anterior segment, including the cornea, sclera, anterior chamber and lens. This section will concentrate on describing the devices available to determine various aspects of the shape of the cornea, limbus and sclera.

Devices that determine corneal shape are often referred to as 'corneal tomographers'. Tomography stems from the Greek words for 'slice' (tomos) and 'describing' (graphia) (Ambrosio et al., 2013). Anterior-segment tomography provides the topography of both the front and back corneal surfaces. A wide variety of methods exist, including those based on horizontal slit scanning (Liu et al., 1999; Rao et al., 2002; Cairns and McGhee, 2005; Swartz et al., 2007; Oliveira et al., 2011), rotational Scheimpflug scanning (Liu et al., 1999; Li et al., 2002; Rao et al., 2002; Charles et al., 2005; Oliveira et al., 2011) and optical coherence tomography (OCT) (Hrynchak and Simpson, 2000; Wang et al., 2002, 2011; Swartz et al., 2007; Haque et al., 2008; Matalia and Swarup, 2013; Rio-Cristobal and Martin, 2014). These devices can broadly be divided into those that determine only anterior corneal shape, those that can determine anterior and posterior corneal shape and finally technologies that can provide information on the cornea, limbus and sclera.

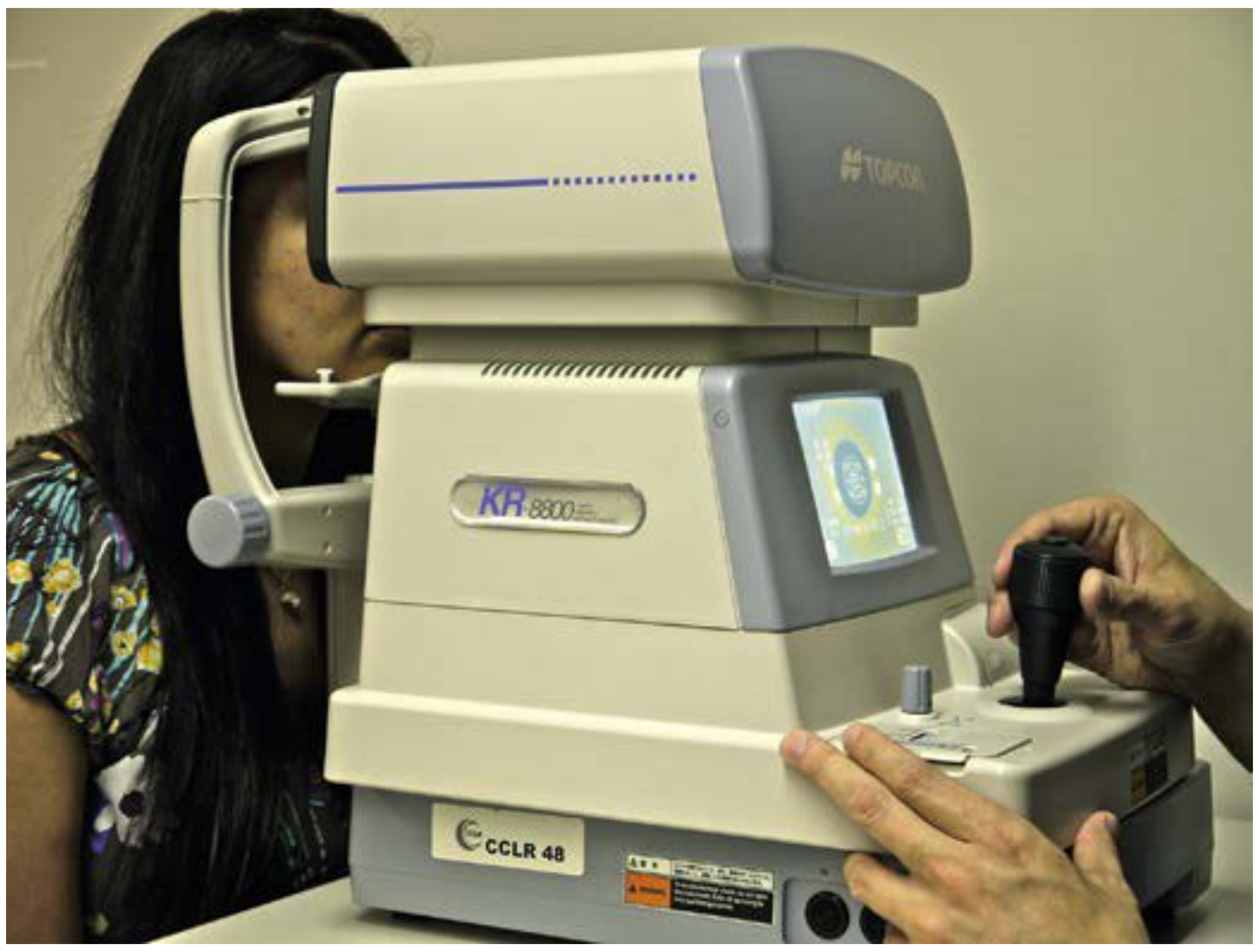


Fig. 36.18 The Topcon KR-8800 Auto Kerato-Refractometer. (Courtesy of Centre for Contact Lens Research and Topcon Medical Systems Inc.)

ANTERIOR CORNEAL SHAPE

Keratometry

Knowledge of corneal curvature is primarily of interest as an aid in determining the initial contact lens to be placed on the eye in cases of rigid contact lens fitting. In addition, an indication of rapid changes in curvature can be indicative of a compromised cornea and also aid in the diagnosis of keratoconus. Measurement of the radius of curvature of the cornea is based on the fact that the front surface of the cornea acts as a convex mirror. The reflection of an object (or mire, from the French for 'target') of known size at a known distance is viewed using a short-focus telescope, and a relatively simple equation allows the corneal front surface radius of curvature to be determined directly from the instrument. The corneal power that results from a given radius is often also indicated on the keratometer; alternatively, this can be calculated (see Appendix D). The optical principles of keratometry, the various types of keratometer available and their specific mode of operation may be obtained from other sources (Stone and Rabbetts, 1994; Henson, 1996b). The actual region over which the standard keratometer measures corneal radius is that of two small areas approximately 1.5 mm on either side of the central fixation point (Stone and Rabbetts, 1994). Different types of keratometer use differently sized mires at differing separations. It is thus of no surprise that different keratometers may give differing radius values on the same eye. Most keratometers in clinical practice now use automated keratometry, using infrared devices that rapidly and automatically determine central keratometry and refractive error simultaneously (Fig. 36.18).

In addition to determining the central radius of curvature, it is useful to measure peripheral radius values, particularly in complicated conditions such as post-penetrating keratoplasty and post-refractive surgery. Conventional keratometers have traditionally been adapted by using peripheral fixation points (Stone and Rabbetts, 1994). However, in reality keratometers cannot be used to determine corneal curvature accurately if the surface being measured does not have a constant radius of curvature or is not radially symmetrical (Stone and Rabbetts, 1994). For this reason, dedicated instruments using other technologies have been developed to measure overall corneal topography.

Corneal Topographic Analysis

The aim of corneal topography (or keratoscopy) is to describe accurately the shape of the corneal surface in all meridians (Mandell, 1992; Guillon and Ho, 1994). In most cases, the technique uses a similar principle to keratometry, in that it determines the size of the image of a target reflected in the corneal surface, the primary difference relating to the fact that for keratoscopy a series of circular concentric targets are used (a Placido disc image). This arrangement allows both central and peripheral curvature to be determined. Historically, a photographic record of the corneal reflection images was made (photokeratoscopy) and measurements calculated subsequently (Veys and Davies, 1995).

Modern-generation topographers capture the image electronically on a computer and use sophisticated image-processing software to provide immediate analysis of the reflected image (videokeratoscopy). Using this technique it has been clearly demonstrated that the cornea is aspheric and can best be described as a flattening ellipse, whose rate of flattening is asymmetrical about its centre (Guillon and Ho, 1994). The history and detailed description of the development and operation of topographers and their clinical applications are described elsewhere (Guillon and Ho, 1994; Dave, 1998; Klyce et al., 1998; Klyce, 2001).

The simplest of topographers are reflective devices, which measure topography based on the reflection of mires from the anterior-surface tear film, which are essentially identical in shape to the corneal surface.

Qualitative Assessment. The most basic reflective device for assessing corneal topography is the Placido disc, which is simply a series of concentric black and white rings on a flat circular disc with a central sight hole. The disc is positioned in front of the cornea and the reflections are observed. Using this method, only gross irregularities in the corneal surface and very high astigmatism can be detected. Improved versions of the Placido disc include the internally illuminated Klein keratoscope, Loveridge grid (Loveridge, 1993) and Tearscope-plus with corneal topography grid attachment (Guillon, 1997).

Quantitative Assessment. Quantitative reflective devices (Fig. 36.19) utilize the same basic principle of projecting a grid on to the cornea. The images are captured with a video camera and a computational approach is adopted to analyse the data and derive a description for the corneal shape. The choice of computational method is important as this will largely dictate the accuracy and validity of the keratoscope. The most frequently utilized computational approach is the 'slope of surface' method (Guillon and Ho, 1994). Basically, devices that use this technology measure slope directly as a function of distance from a central reference axis and derive curvature from these results. It is important to note that these distance-based instruments are only estimating the average shape of the cornea, since the algorithms are based on a radially symmetrical surface, which does not accurately describe the cornea. These axial or sagittal measurements result in an underestimation of the radius of curvature in areas that may be steeper than the central cornea, and an overestimation in areas that are flatter. More recently, the algorithms have been modified and are now generally based on the radius of curvature, in an attempt to provide a better estimate of the local shape of the cornea.

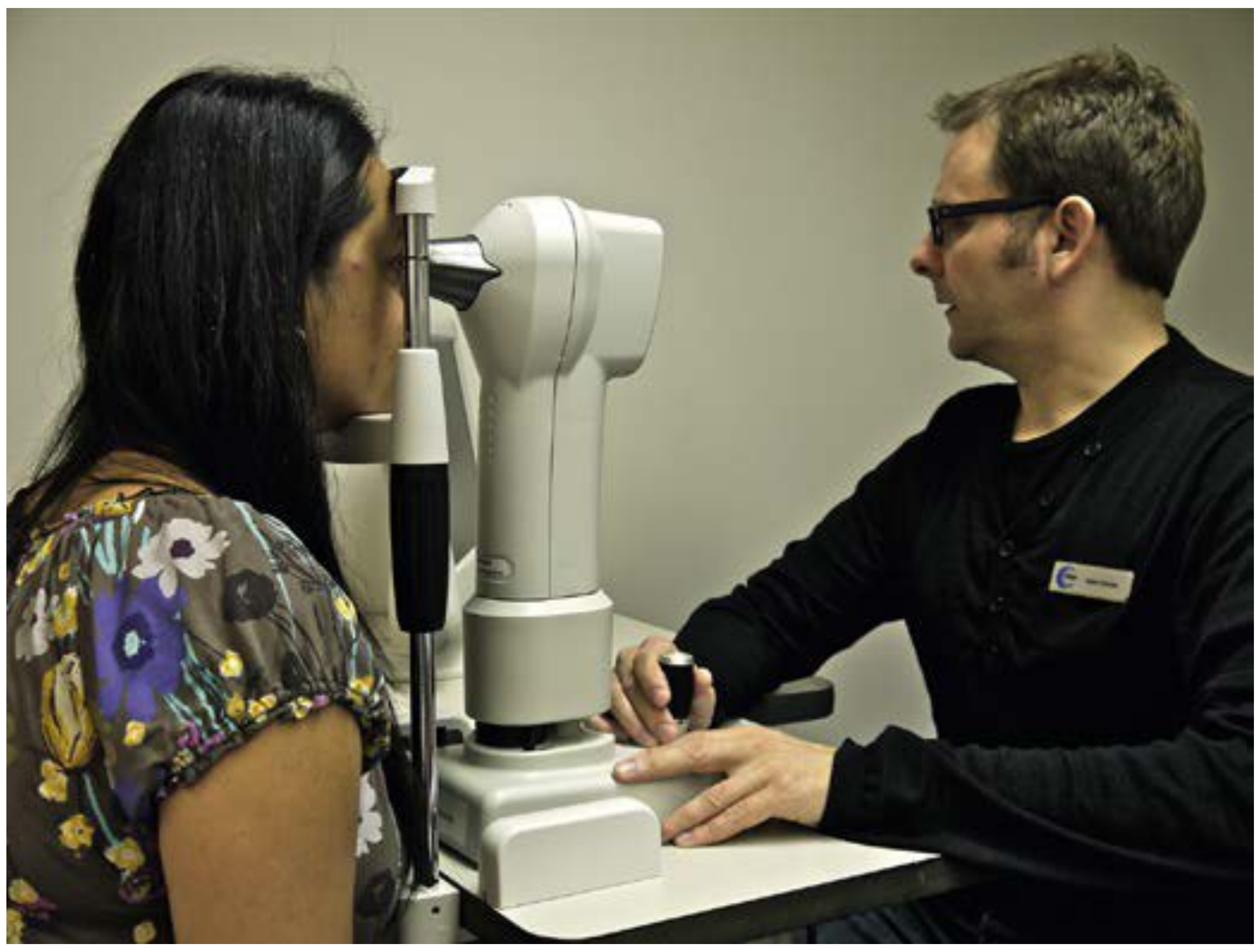


Fig. 36.19 The Medmont E300 corneal topographer. This is an example of a small cone topographer that uses a reflective technique to obtain topographic data. (Courtesy of Centre for Contact Lens Research and Medmont International Pty Ltd.)

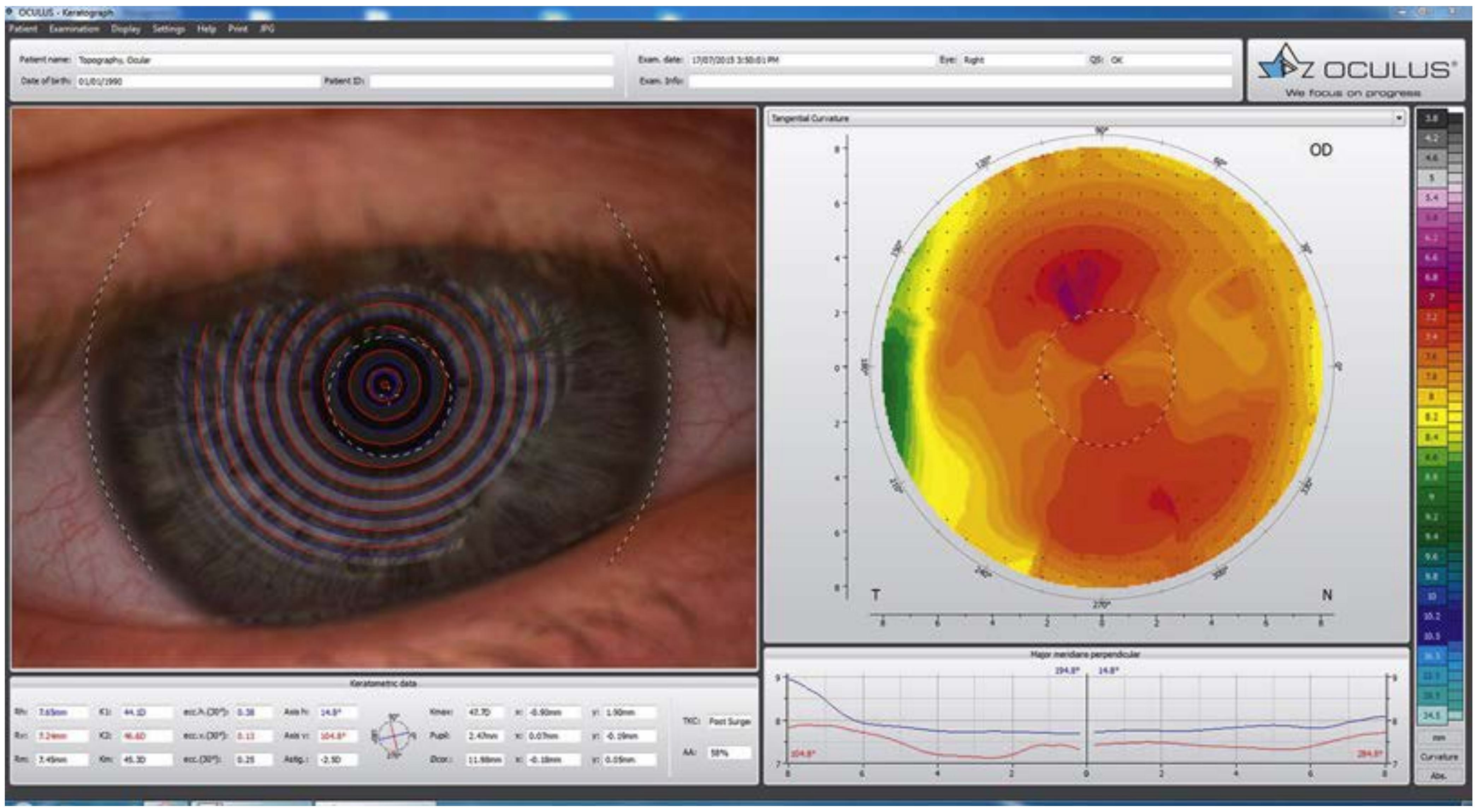
The images (or 'maps') produced by reflective or Placido-based keratoscopes display the power distribution of the corneal surface using colour-coded displays, in which greens and yellows represent powers characteristic of those found in normal corneas, blues or cooler colours represent flatter areas (low powers) and reds or hotter colours represent steep areas (high powers) (Klyce et al., 1998). These maps permit recognition of corneal shape through pattern recognition and swiftly reveal the presence of abnormal powers (Fig. 36.20). All devices display simulated keratometry values, which are analogous to standard keratometry values, and simultaneously display the power and axis of the flattest meridian.

A number of manufacturers now produce hand-held topographers. These portable devices can prove very useful for examining children, older people or those with restricted mobility, and for use in off-site consultations.

ANTERIOR AND POSTERIOR CORNEAL SHAPE

Reflective devices, described above, are limited to determining the shape of the anterior corneal surface only. A range of instruments are available which allow tomographic imaging – a process whereby a series of two-dimensional images are reconstructed into three-dimensional images using technology such as slit scanning, Scheimpflug imaging and optical coherence tomography (OCT).

In eyes that continue to progress to corneal ectasia, changes in the posterior cornea are considered to be an early indicator of the condition, prior to the anterior cornea showing signs of change (Tomidokoro et al., 2000; Belin and Ambrosio, 2013; de Sanctis et al., 2013). Therefore, assessment of the posterior corneal shape and topographic thickness are becoming increasingly valuable in clinical practice.


OCULUS - Keratograph
Patient Examination Display Settings Help Print JPG
OCULUS® We focus on progress
Tangential Curvature
OD
T
N
Keratometric data
Major meridians perpendicular

Patient name: Topography, Ocular
Date of birth: 01/01/1990
Patient ID:
Exam. date: 17/07/2015 3:50:01 PM
Eye: Right
QS: OK
Exam. Info:

Rh: 7.65mm K1: 44.1D ecc.h.(30°): 0.38 Axis h: 14.8°
Rv: 7.24mm K2: 46.6D ecc.v.(30°): 0.13 Axis v: 104.8°
Rm: 7.45mm Km: 45.3D ecc.(30°): 0.25 Astig.: -2.5D
Kmax: 47.7D x: -0.90mm y: 1.00mm
Pupil: 2.47mm x: 0.07mm y: -0.19mm
Dcor.: 11.98mm x: -0.18mm y: 0.05mm
TKC: Post Surge
AA: 58%

Fig. 36.20 Corneal topography map of a highly myopic eye with astigmatism, taken with the Keratograph 5M. The steep corneal curvature and astigmatism can be clearly seen on this tangential map.

Slit-scanning Devices

Currently, the only device that uses horizontal slit-scanning methods to obtain anterior-segment data is the Orbscan II (Bausch & Lomb). This device combines both Placido disc and slit-scanning technologies to obtain topographic measurements of both anterior and posterior corneal surfaces, in addition to the anterior lens and iris (Cairns and McGhee, 2005; Swartz et al., 2007; Oliveira et al., 2011; Rio-Cristobal and Martin, 2014; Pinero, 2015). The instrument scans across the anterior corneal surface, obtaining 40 sequential slit images, whilst simultaneously recording eye movements and reflection data from a Placido disc device. The data are then reassembled into a three-dimensional reconstruction of the anterior and posterior corneal surface (Cairns and McGhee, 2005; Swartz et al., 2007; Oliveira et al., 2011; Rio-Cristobal and Martin, 2014; Pinero, 2015).

The instrument differs from traditional keratoscopes in that it uses a combination of slit-scan triangulation and surface reflection to determine corneal shape. Specifically, this instrument unifies triangulated and reflective data to obtain accurate measurements of elevation, slope and curvature. In addition to conventional axial and tangential maps, shape data can be displayed as an elevation map, in which the relative height of the cornea is compared with a spherical reference surface. Elevations above the reference sphere are red coloured and depressions below the reference sphere are coloured blue.

Scheimpflug Imaging Devices

Scheimpflug imaging devices operate on a method patented by Theodor Scheimpflug (an Austrian Army Captain, who used it to correct perspective distortion in aerial photographs) in 1904. Compared with traditional photographic techniques where the three planes (the film, the lens and the plane of focus) are parallel to one another, in Scheimpflug imaging the planes are not parallel. Instead, the plane of the lens is tilted such that it intersects both the film plane and focal plane, which extends the depth of focus, allowing imaging from the anterior corneal surface to the posterior lens surface. This technique enables landscape and architectural photographers to use large-format cameras with very long focal lengths (and shallow depth of focus) to dramatically extend depth of field without using a small aperture.

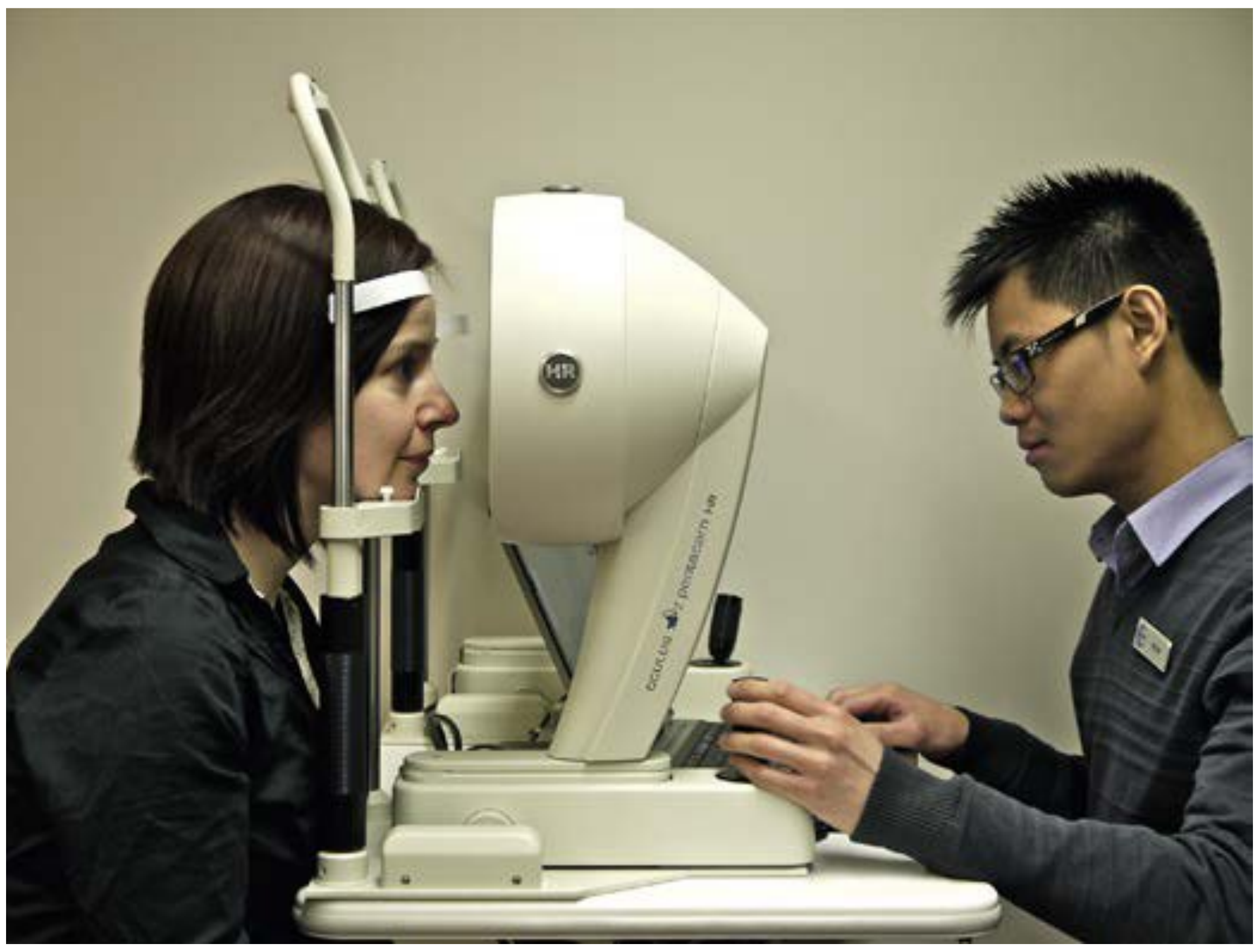
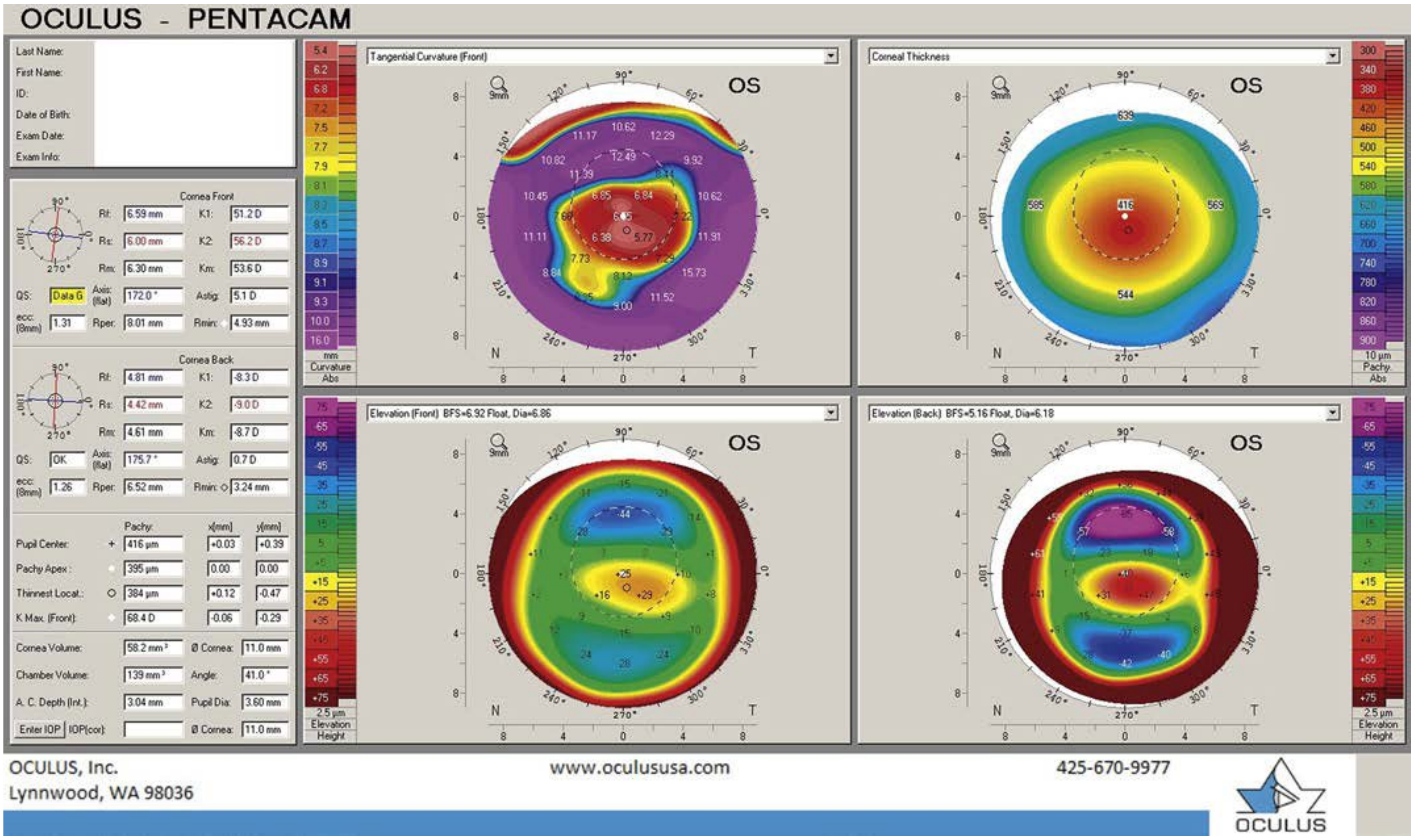


Fig. 36.21 The OCULUS Pentacam HR in use. (Courtesy of Centre for Contact Lens Research and Oculus.)

The Pentacam (Oculus) was the first instrument to use a rotational Scheimpflug camera to provide three-dimensional, non-contact imaging of the anterior segment (Ambrosio et al., 2013). The instrument (Fig. 36.21) uses a 475 nm blue light source and two camera systems to capture an image. The rotational Scheimpflug camera takes up to 50 cross-sectional images on an angle from 0 to 180° in a single scan, acquiring 25 000 data points in approximately 2 seconds. The second camera is static and used to monitor eye fixation and detects pupil size. The software supplied with the Pentacam utilizes an algorithm that corrects for any image distortion that is encountered from the optics of the camera system and the optics of the anterior segment being imaged (Wegener and Laser-Junga, 2009). As the



OCULUS - PENTACAM

Last Name:
First Name:
ID:
Date of Birth:
Exam Date:
Exam Info:

Cornea Front

		Rf:	6.59 mm	K1:	51.2 D
		Rs:	6.00 mm	K2:	56.2 D
		Rm:	6.30 mm	Km:	53.6 D
QS:	Data G	Axis: (flat)	172.0 °	Astig:	5.1 D
ecc: (8mm)	1.31	Rper:	8.01 mm	Rmin:	4.93 mm

Cornea Back

		Rf:	4.81 mm	K1:	-8.3 D
		Rs:	4.42 mm	K2:	-9.0 D
		Rm:	4.61 mm	Km:	-8.7 D
QS:	OK	Axis: (flat)	175.7 °	Astig:	0.7 D
ecc: (8mm)	1.26	Rper:	6.52 mm	Rmin:	3.24 mm

	Pachy:	x[mm]	y[mm]
Pupil Center: +	416 µm	+0.03	+0.39
Pachy Apex:	395 µm	0.00	0.00
Thinnest Locat.: ○	384 µm	+0.12	-0.47
K Max. (Front):	68.4 D	-0.06	-0.29

Cornea Volume:	58.2 mm³	Ø Cornea:	11.0 mm
Chamber Volume:	139 mm³	Angle:	41.0 °
A. C. Depth (Int.):	3.04 mm	Pupil Dia:	3.60 mm
Enter IOP IOP(cor):		Ø Cornea:	11.0 mm

Tangential Curvature (Front)
OS
mm Curvature Abs
Corneal Thickness
OS
10 µm Pachy Abs
Elevation (Front) BFS=6.92 Float, Dia=6.86
OS
2.5 µm Elevation Height
Elevation (Back) BFS=5.16 Float, Dia=6.18
OS
2.5 µm Elevation Height
N
T
90°
270°

OCULUS, Inc.
Lynnwood, WA 98036

www.oculususa.com

425-670-9977

OCULUS

Fig. 36.22 Pentacam data from a keratoconic with a centrally located cone. (Image courtesy of Lacey Haines.)

instrument uses a rotating camera, accurate measurements can be obtained from highly irregular corneas that reflective Placido-based systems struggle to image accurately.

For the purposes of corneal shape assessment, the Pentacam presents the data in the form of anterior and posterior sagittal (axial) and tangential curvature, refractive power maps and anterior and posterior elevation maps (Fig. 36.22). Similar to the Orbscan, the maps generated are colour coded according to elevations or depressions relative to a reference body, which may be selected as a best-fit sphere, an ellipse of revolution or toric.

Several studies have shown the Pentacam to have greater accuracy in the assessment of posterior corneal elevation than the Orbscan in postoperative corneas, as light scattering could affect Orbscan image acquisition (Boscia et al., 2002; Ha et al., 2009; Rio-Cristobal and Martin, 2014).

CORNEAL AND SCLERAL SHAPE

Eye Surface Profiler (Eaglet-Eye)

The refractive and therapeutic indications for fitting large-diameter rigid gas-permeable lenses, semiscleral and scleral contact lenses are varied. For optimum performance and ocular health, these lenses require specific fitting principles to be adhered to. To assist with the fitting procedure, an understanding of the corneal and scleral shape profile is imperative. Typical methods of assessing the topography of the ocular surface have previously been limited to corneal topography, which is of little benefit when fitting scleral lenses, as they rest on the sclera and vault the cornea (Schornack and Patel, 2010).

The Eye Surface Profiler (ESP) (Eaglet-Eye, 2015) is the first instrument capable of measuring the curvature and sagittal height up to 20 mm diameter, which covers the cornea, corneo-limbal junction and sclera (Fig. 36.23). The instrument uses a double projection Fourier transform profilometer that is capable of determining the curvature and elevation of the anterior eye beyond the corneal region. Imaging the anterior eye shape requires the instillation of sodium fluorescein, onto which a grid pattern is projected. As Fourier transform profilometry is a projection technique, the anterior surface of the eye is visualized directly. This minimizes any topographic distortions that are encountered with reflection techniques such as those that use Placido discs (Simón-Castellvi et al., 2010).

Anterior-segment Optical Coherence Tomography (AS-OCT)

OCT is a non-contact optical imaging technique that is capable of high-resolution micrometer-scale cross-sectional imaging of biological tissue using infrared light (Böhnke and Masters, 1999; Hrynchak and Simpson, 2000; Swartz et al., 2007; Simpson and Fonn, 2008; Ramos and Huang, 2009; Maeda, 2010; Wang et al., 2011; Rio-Cristobal and Martin, 2014).

The technique uses Michelson interferometry to compare a partially coherent reference beam to one reflected from tissue. The two beams are combined and interference between the two light signals occurs only when their path lengths match to within the coherence length of light. The magnitude and distance within the tissue of the reflected or back-scattered light at a single point are determined using a mirror system to form a reflectivity profile (or an A-scan, analogous to ultrasound) (Izatt et al., 1994; Fujimoto et al., 1995, 1998). A tomographic

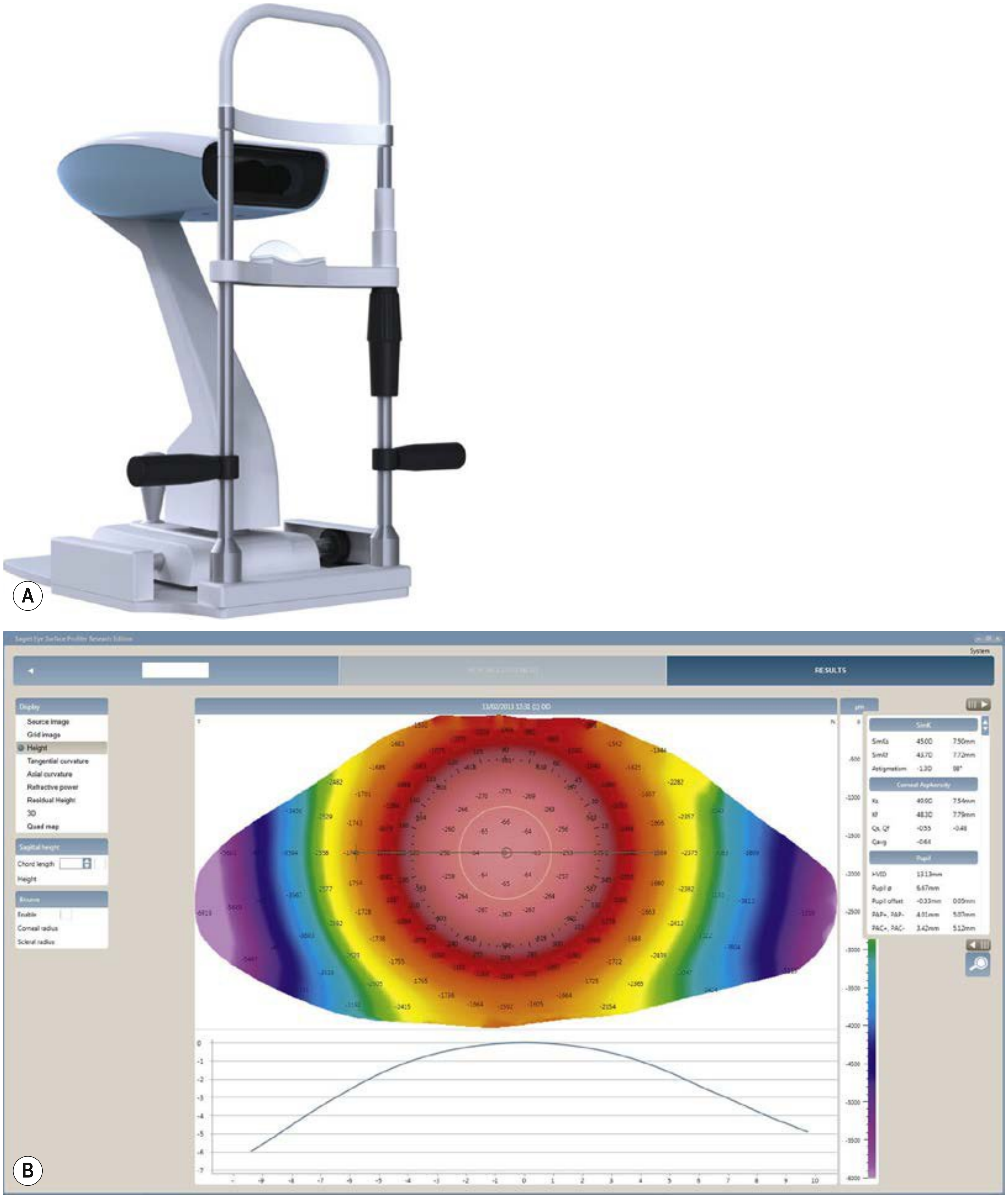

A
B
Display
Source image
Grid image
Height
Tangential curvature
Axial curvature
Refractive power
Residual Height
3D
Quad map
Chord length
Height
Enable
Corneal radius
Scleral radius
RESULTS
System
SimK
Corneal Asphericity
Pupil

Fig. 36.23 (A) Eye Surface Profiler (Eaglet-Eye); (B) Sagittal height map across the corneal, limbal and scleral regions imaged using the ESP. (Image courtesy of Lee Hall.)

image, a B-scan, is generated by assembling multiple A-scans. The technique of 2D-OCT is thus analogous to ultrasound B-mode imaging, except that it uses light rather than sound, and provides the data for the computer analyser by utilizing the differential reflectivity to coherent laser light, of transparent ocular tissues. Reflections occur at boundaries between materials of differing refractive indices, and the greater the difference in index the greater is the amplitude of the reflected signal. The 2D-OCT scans are subsequently processed by a computer, which corrects for any axial eye movement artefacts that have occurred during the acquisition time. The B-scan represents a cross-sectional view of the structure under investigation, similar in appearance to a histological section.

OCT was initially used to image retinal complications, in which tissues had become separated or changed in structure. These include macular oedema, macular holes, posterior vitreous detachment, retinal detachment, retinoschisis and optic nerve head changes (Hrynchak et al., 2000; Bajwa et al., 2015). Imaging of the anterior segment with OCT was first described in 1994 (Izatt et al., 1994). All of the original papers using OCT to examine the anterior ocular surface relied upon the modification of OCT devices that were developed to image the retina.

Commercially available OCTs with anterior-segment (AS) imaging capabilities are now commonplace. With resolutions between 2 and 20 µm, AS-OCT is increasingly being used to examine the cornea and has proven useful in determining epithelial and total corneal thickness changes following refractive surgery, assessing corneal central and average thickness in cases of ocular hypertension and glaucoma, and in patients with corneal oedema (Hrynchak and Simpson, 2000; Maldonado et al., 2000; Wang et al., 2002, 2006b; Lee et al., 2003; Haque et al., 2004, 2008; Iester et al., 2009; Dorairaj et al., 2012). AS-OCT is a useful tool to diagnose and document changes in corneal health. It can be used to monitor corneal infections, dystrophies and degenerations (Konstantopoulos et al., 2008; Vajzovic et al., 2011; Utsunomiya et al., 2014), and in the assessment of glaucoma risk factors such as central corneal thickness and narrow anterior-chamber angles (Lee et al., 2003; Iester et al., 2009; Dorairaj et al., 2012).

For the contact lens practitioner, AS-OCT can be very useful during both contact lens fitting and assessment. Peripheral corneal and corneo-scleral topography can assist in the prediction of soft lens fit, and the interaction of the lens edge with the conjunctiva can be quantitatively assessed (Hall et al., 2011; Shen et al., 2011; Wolffsohn et al., 2013; Turhan and Toker, 2015). This technology can also assist with complex contact lens design and fitting, including keratoconic RGP fitting (Elbendary and Abou Samra, 2013) and when designing and fitting large diameter RGP and scleral contact lenses (Gemoules, 2008; van der Worp, 2010; Choi et al., 2014). The ability to measure the space between the cornea and the back surface of the scleral lens (the vault) using on-screen calipers and visualize the position of the landing zone of the lens on the conjunctiva permits rapid and accurate fit modifications (van der Worp, 2010; Sonsino and Mathe, 2013; van der Worp et al., 2014).

Three types of OCTs are available for anterior-segment imaging: time domain, spectral domain and swept source scanning. The differences in data acquisition and processing for these technologies will be briefly discussed.

Time-domain OCT. In time-domain OCT (TD-OCT), a movable reference mirror is used to reflect the light source to generate a series of images. By taking a series of 2000 A-scans per second, a reflectivity profile is generated and the depth of ocular tissues is determined (Penner and Guillermo, 2007; Maeda, 2010).

One example of such a device is the Visante® AS-OCT (Carl Zeiss Meditec, Inc.). The Visante OCT uses 1310 nm light, which allows for deeper penetration into the tissues to allow greater cross-sectional visualization and imaging of the anterior chamber (Fig. 36.24) (Penner and Guillermo, 2007; Ramos and Huang, 2009) without occlusion of the angle by the scleral spur. Measurement tools incorporated into the device enable direct measurement of a variety of anterior-segment ocular structures, including corneal thickness, corneal flap thickness and residual stromal thickness following laser in situ keratomileusis (LASIK) surgery, anterior-chamber depth (ACD), anterior-chamber angles and anterior-chamber diameter. The instrument can also be used to model the positioning of implantable contact lenses and intraocular lenses.

Spectral-domain (Fourier-domain) OCT. Whereas TD-OCT uses a moving reference mirror to reflect near-infrared light, spectral-domain OCT (SD-OCT) (also referred to as Fourier-domain; FD-OCT) uses a fixed reference mirror to reflect the light source. The interference between the ocular tissue and the reference reflections is detected by a spectrometer; it is then Fourier transformed to generate an A-scan (Ramos and Huang, 2009; Arita et al., 2013; Rio-Cristobal and Martin, 2014). SD-OCTs use wavelengths of 820–879 nm, which allows improved axial resolution of images (5 µm compared with 17 µm). However, the longer wavelength used in TD-OCTs allows deeper tissue penetration, to image anterior-segment structures better (Sarunic et al., 2008; Ramos and Huang, 2009; Maeda, 2010; Rio-Cristobal and Martin, 2014). As the production of A-scans are not dependent upon a moving reference mirror, the speed of image acquisition with SD-OCTs is comparatively faster than TD-OCT, acquiring 25 000– 50 000 A-scans per second (Ramos and Huang, 2009; Maeda, 2010). An additional feature of SD-OCT is the production of a series of parallel B-scans from which 3D images can be generated akin to three-dimensional topography, which can then be rotated and otherwise manipulated.

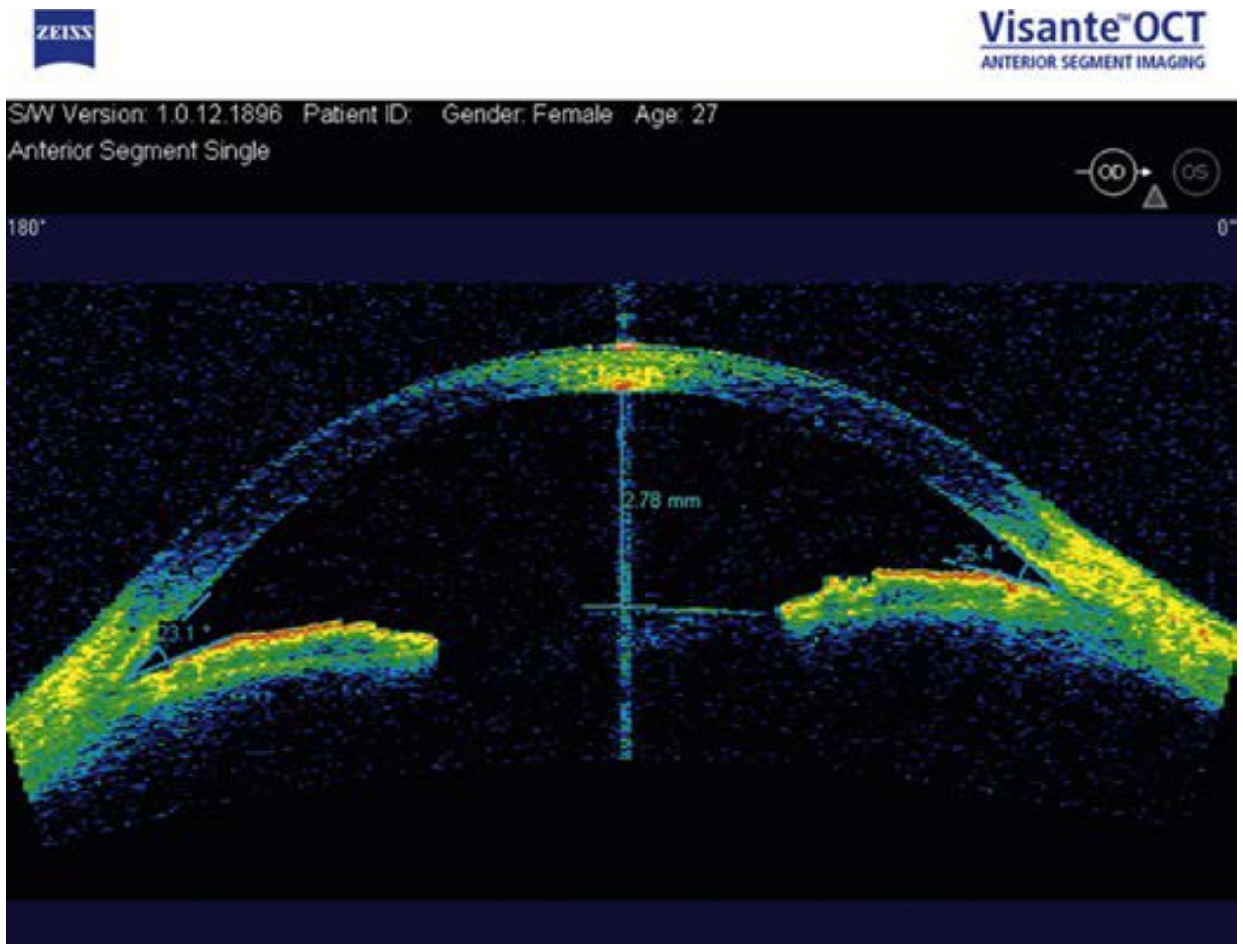


Fig. 36.24 Imaging mode for the Visante anterior-segment optical coherence tomography (AS-OCT), demonstrating various anterior-segment parameters.

Examples of SD-OCT devices include the 3D OCT-1000, -2000 and Maestro (Topcon Medical Systems Inc., Oakland, CA, USA), Cirrus HD-OCT (Carl Zeiss Meditec, Inc., Dublin, OH, USA), iVue-100 (Optovue, Fremont, CA, USA), and SPECTRALIS® SD-OCT (Heidelberg Engineering GmbH, Heidelberg, Germany).

Swept-source OCT. SD-OCT is one type of FD-OCT (Sarunic et al., 2008; Maeda, 2010). A second type of FD-OCT is swept-source OCT (SS-OCT), which uses a longer wavelength of 1050 nm, permitting deeper penetration into tissues and allowing imaging with enhanced visualization of the anterior segment. SS-OCT is the latest technology used in commercially available OCT instruments. This technology uses a tunable laser that scans through a range of wavelengths of the light source to generate an interferogram. The interferogram is Fourier transformed to produce an A-scan, and several A-scans are assembled to form the cross-sectional B-scan. The scans are of high resolution, with photodetectors replacing CCD cameras to further increase resolution to 1 µm and overall scan acquisition time is faster than with SD-OCT (up to 108 000 scans per second), which reduces any artefacts arising from eye movements (Maeda, 2010; Karnowski et al., 2011). For this reason, this instrumentation is also referred to as high-speed swept-source OCT (Karnowski et al., 2011). Anterior-segment OCT imaging modules also incorporate anterior and posterior corneal topography. Commercially available instruments currently include the Topcon DRI OCT Triton (Topcon Medical Systems Inc.; Fig. 36.25) and the SS-1000 CASIA OCT (Tomey Corporation, Nagoya, Japan).

Developments in AS-OCT technology have significantly enhanced clinicians' ability to image the anterior segment and

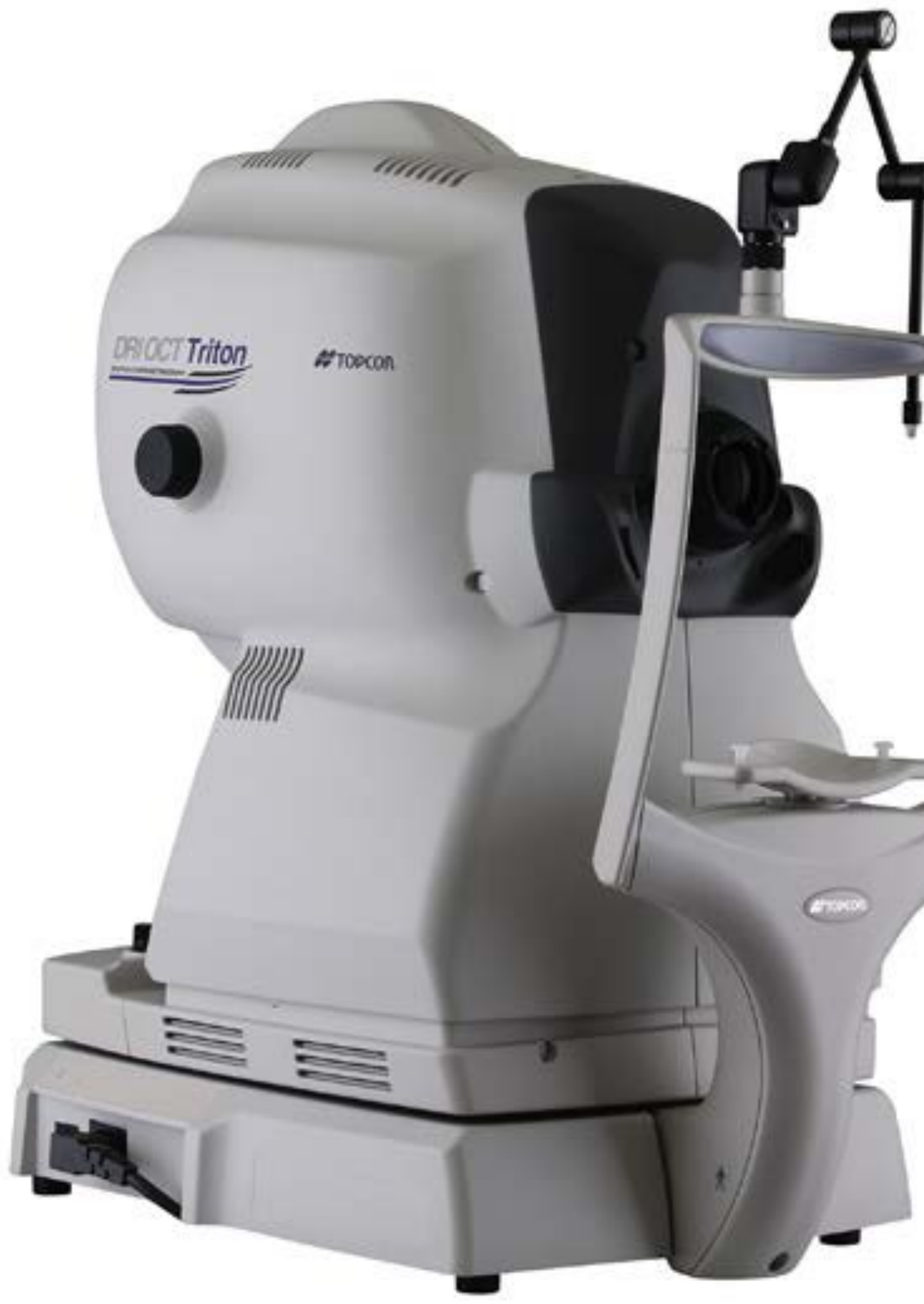


Fig. 36.25 Topcon DRI OCT Triton, Swept source OCT. (Courtesy of Topcon Medical Systems Inc.)

such devices are rapidly becoming an irreplaceable tool within clinical practice for those involved in contact lens fitting and anterior-segment disease management.

Determination of Corneal Thickness

Historically, measurement of central corneal thickness was most commonly used to assess corneal oedema following contact lens wear and in keratoconic patients both for diagnosis and to monitor the progression of corneal thinning. However, the growth of refractive surgery has resulted in an ever-increasing need for accurate assessment of corneal thickness across the entire cornea. This thickness measurement is useful in the diagnosis of patients at greater risk of developing ectasia (Rad et al., 2004; Caster et al., 2007), for customized corneal laser treatments (Reinstein et al., 2012) and in corneal cross-linking surgery (Padmanabhan and Dave, 2013; Chunyu et al., 2014). In addition, the importance of corneal thickness in the diagnosis and ongoing treatment of patients with glaucoma (Lee et al., 2003; Iester et al., 2009) has resulted in corneal thickness assessment becoming a routine assessment in clinical practice.

OPTICAL PACHYMETRY

Optical pachymetry is based on the measurement of the apparent thickness of an optical section of the cornea, and its popularity is largely based on the commercial availability of a pachymeter attachment for the Haag–Streit slit lamp. First, a split-image device is inserted into one eyepiece of the slit lamp. The method depends upon the relative rotation of two glass plates, which are placed one on top of the other. Rotation of the upper plate moves the upper half of the image of the cornea with respect to the fixed lower half. When the endothelium of the upper field is aligned with the epithelium of the lower field, the angle of rotation of the upper plate is read off an externally positioned scale. This measurement is proportional to the apparent thickness of the cornea, with true corneal thickness being determined by means of a conversion table.

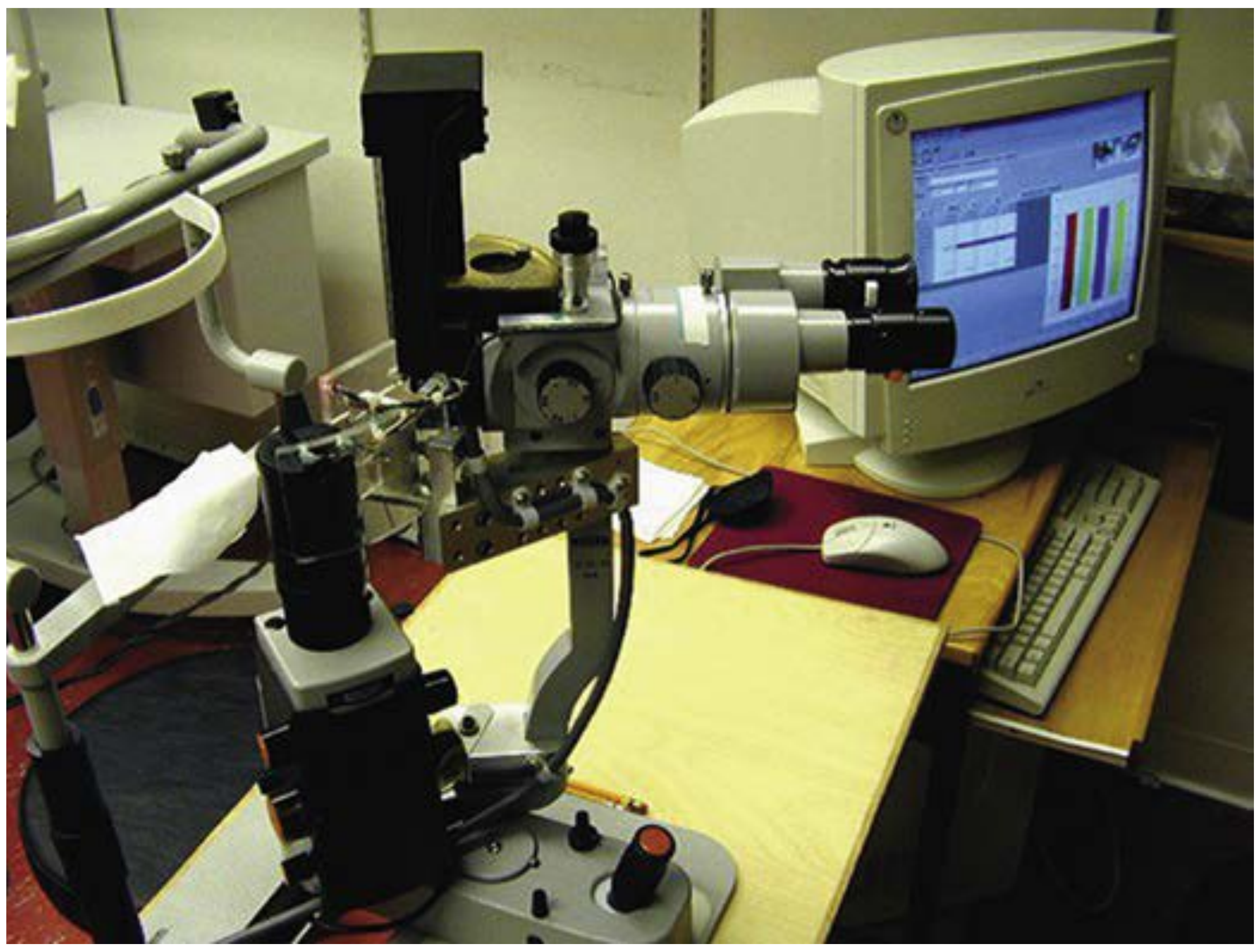


Fig. 36.26 A computerized optical pachymeter. The pachymeter is connected to a potentiometer that is directly linked to a custom written software program that analyses the data. (Courtesy of Centre for Contact Lens Research and Vistakon / Johnson & Johnson.)

Although perfectly acceptable for clinical purposes, the arrangement described above is too inaccurate for research purposes. A number of modifications to the technique (Chan-Ling and Pye, 1994) have resulted in an accuracy of approximately 5 μm being reported. Two such modifications include the use of two or four small light sources to ensure that the incident beam is normal to the corneal surface (Mishima and Hedbys, 1968), and an arrangement whereby the rotation of the glass plate is coupled to a potentiometer such that the angle of rotation is directly converted into an electrical signal, allowing it to be immediately input into a computer program (Fig. 36.26). This enables more rapid data collection, efficient file management and more accurate, repeatable data collection. More detailed information concerning these modifications and potential errors in optical pachymetry can be obtained from other sources (Chan-Ling and Pye, 1994; Henson, 1996a, 1996b). Optical pachymetry remains a standard method to determine corneal thickness, particularly in contact lens studies examining corneal swelling (Holden et al., 1984; Stapleton et al., 1998; Fonn et al., 1999; Gifford et al., 2011; Agarwal et al., 2012; Moezzi et al., 2015).

ULTRASONIC PACHYMETRY

With the rapid increase in interest in refractive surgery and the knowledge of the impact of corneal thickness on intraocular pressure readings (Lee et al., 2003; Iester et al., 2009), it has become necessary for refractive surgeons to obtain rapid, repeatable measurements of corneal thickness. In many cases this measurement is undertaken by support staff, who often have minimal slit-lamp skills. These factors have resulted in the development of simpler methods for the assessment of corneal thickness, and ultrasonic pachymetry has become the method of first choice in many practice settings (Rio-Cristobal and Martin, 2014) and has also been extensively used in a research setting (Gherghel et al., 2004; Javaloy et al., 2004; McLaren et al., 2004; Swartz et al., 2007; Zhao et al., 2007a; Almubrad et al.,

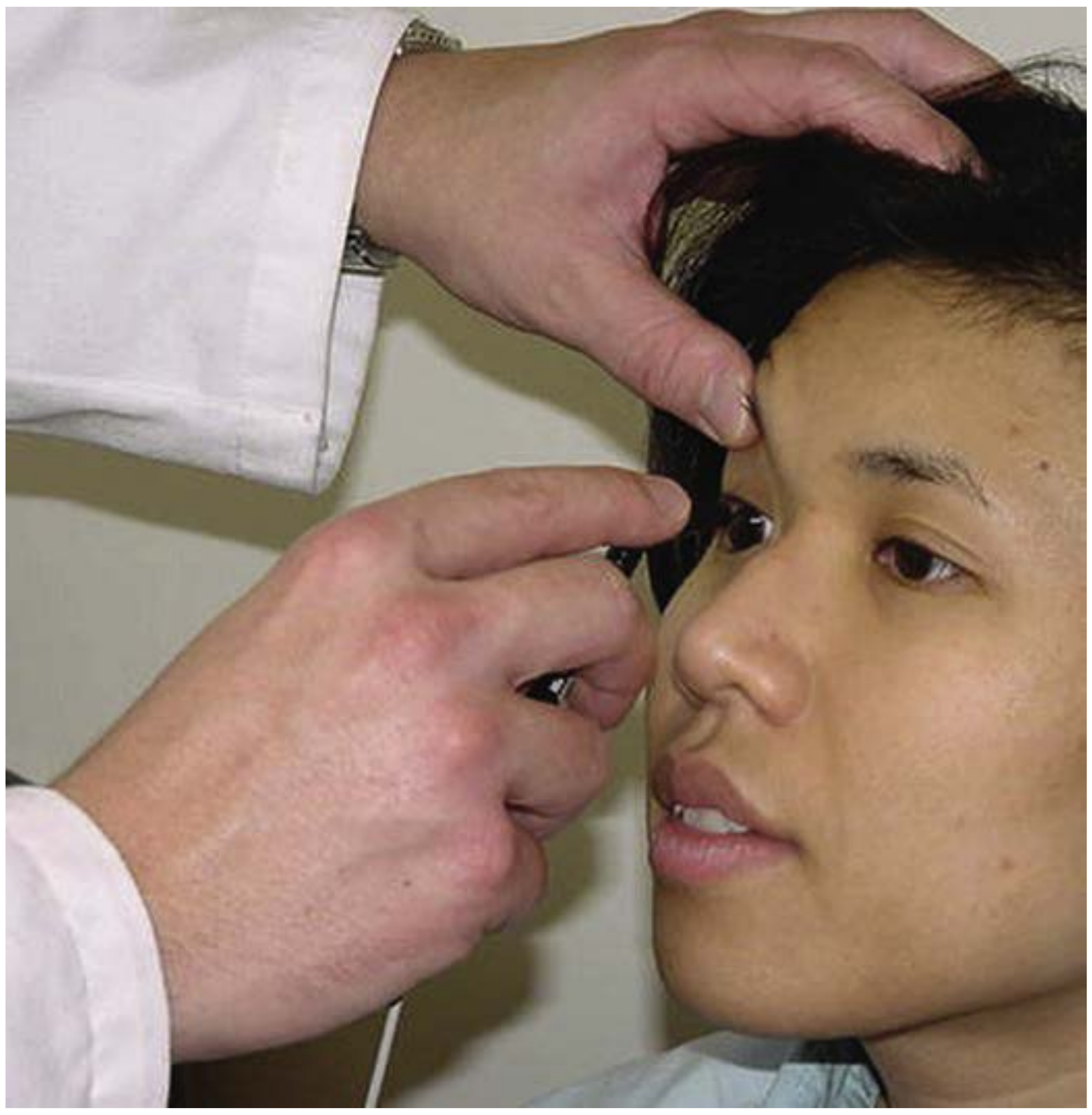


Fig. 36.27 An ultrasonic pachymeter evaluation. The eye is anaesthetized and the probe touched to the cornea. Readings are digitally recorded once the angle of inclination of the probe is correct.

2011; Williams et al., 2011; Agarwal et al., 2012; Maresca et al., 2014; Rio-Cristobal and Martin, 2014).

The ultrasonic pachymeter is based on traditional A-scan ultrasonography, where the recording is in one dimension only, as compared with B-scan instruments, which provide a two-dimensional view of the eye. Ultrasound is transmitted to the eye from a transducer. Sound is reflected back to the transducer from tissue interfaces, which possess different acoustic impedances, enabling the distance from the ultrasound probe at the anterior epithelial interface to determine the distance between itself and the endothelium–aqueous interface. The transducer determines the time difference between the pulse signals obtained at the two interfaces and computes the corneal thickness based on this time delay and the velocity of sound in corneal tissue, which is approximately 1580 m/s at body temperature (Chan-Ling and Pye, 1994). A direct measurement of corneal thickness is then displayed on a digital readout. Prior to undertaking ultrasonic pachymetry, the cornea is anaesthetized and the patient is slightly reclined (Fig. 36.27).

Potential sources of error in measuring corneal thickness include holding the probe at an oblique angle to the cornea and measuring away from the central corneal apex, both of which would result in elevated readings of central corneal thickness (because corneal thickness increases from the centre to the periphery). The majority of modern instruments include a mechanism whereby a reading is not displayed if the probe is positioned such that there is excessive deviation from the perpendicular.

ANTERIOR-SEGMENT OPTICAL COHERENCE TOMOGRAPHY (AS-OCT)

The technology behind AS-OCT techniques has been described previously. Anterior-segment OCT provides non-contact topographic corneal thickness measures and has been extensively used to report central and peripheral total corneal thickness values in normal subjects, diseased corneas, pre- and post-surgery, epithelial thickness and for those at risk of glaucoma (Maldonado et al., 2000; Wang et al., 2002; Lee et al., 2003; Fishman et al., 2005; Leung et al., 2006; Zhao et al., 2007b; Li et al., 2008; Iester et al., 2009; Prakash et al., 2009; Prospero Ponce et al., 2009; Dorairaj et al., 2012; Li et al., 2012; Neri et al., 2012; Qin et al., 2013; Kanellopoulos and Asimellis, 2014) (Fig. 36.28). AS-OCT also permits the measurement of corneal thickness with a contact lens in situ, making it an accessible procedure for monitoring corneal swelling in contact lens wearers (Martin et al., 2007).

SLIT-SCANNING DEVICES

As previously described, in addition to assessing the shape of the anterior surface of the cornea, the Orbscan II instrument determines posterior surface shape. Corneal thickness is determined by calculating the differences in elevation between the anterior and posterior surfaces of the cornea to generate a pachymetry map (Yaylali et al., 1997; Liu et al., 1999; Auffarth et al., 2000; Chakrabarti et al., 2001; Rao et al., 2002; Radford et al., 2004; Arce et al., 2007; Ortiz et al., 2014). Central corneal thickness (CCT) measurements using the Orbscan II are approximately 7% greater than those obtained using the gold-standard technique, ultrasound pachymetry (Doughty and Jonuscheit, 2010). As a result, an acoustic factor (AF) can be applied to the default output values so that the CCT values obtained with the Orbscan are in closer agreement with values obtained using ultrasound pachymetry. A correction factor of 0.92 is the default selected by the manufacturer and is applied to the entire map. However, its use is controversial as it can cause the CCT value to be up to 7% lower than ultrasound pachymetry (Doughty and Jonuscheit, 2010). As the level of agreement between ultrasound pachymetry and CCT measurements obtained by Orbscan II is limited, several authors have suggested not applying the AF (Lu et al., 2006; Jonuscheit and Doughty, 2007; Martin et al., 2011).

SCHEIMPFLUG SCANNING

Scheimpflug cross-sectional imagers such as the Pentacam use a rotating Scheimpflug camera to capture a series of optical cross-sections of the anterior segment, which are then merged to form a 3D reconstruction. Pachymetry using Scheimpflug scanning instruments are obtained from raw corneal elevation data. Subsequent analysis of these images permits assessment of corneal thickness (Barkana et al., 2005; Lackner et al., 2005; Amano et al., 2006; Fujioka et al., 2007; Mencucci et al., 2012; Park et al., 2012; Belin and Ambrosio, 2013; Guler et al., 2014; Reddy et al., 2014; Wong et al., 2014). Several studies have shown good agreement between CCT values obtained with the Pentacam and ultrasound pachymetry (Oliveira et al., 2011).

CONFOCAL MICROSCOPY

The confocal microscope can obtain three-dimensional corneal data. Using a two-dimensional depth intensity profile, epithelial and corneal thickness can be estimated by measuring the distance between peaks corresponding to the epithelial and

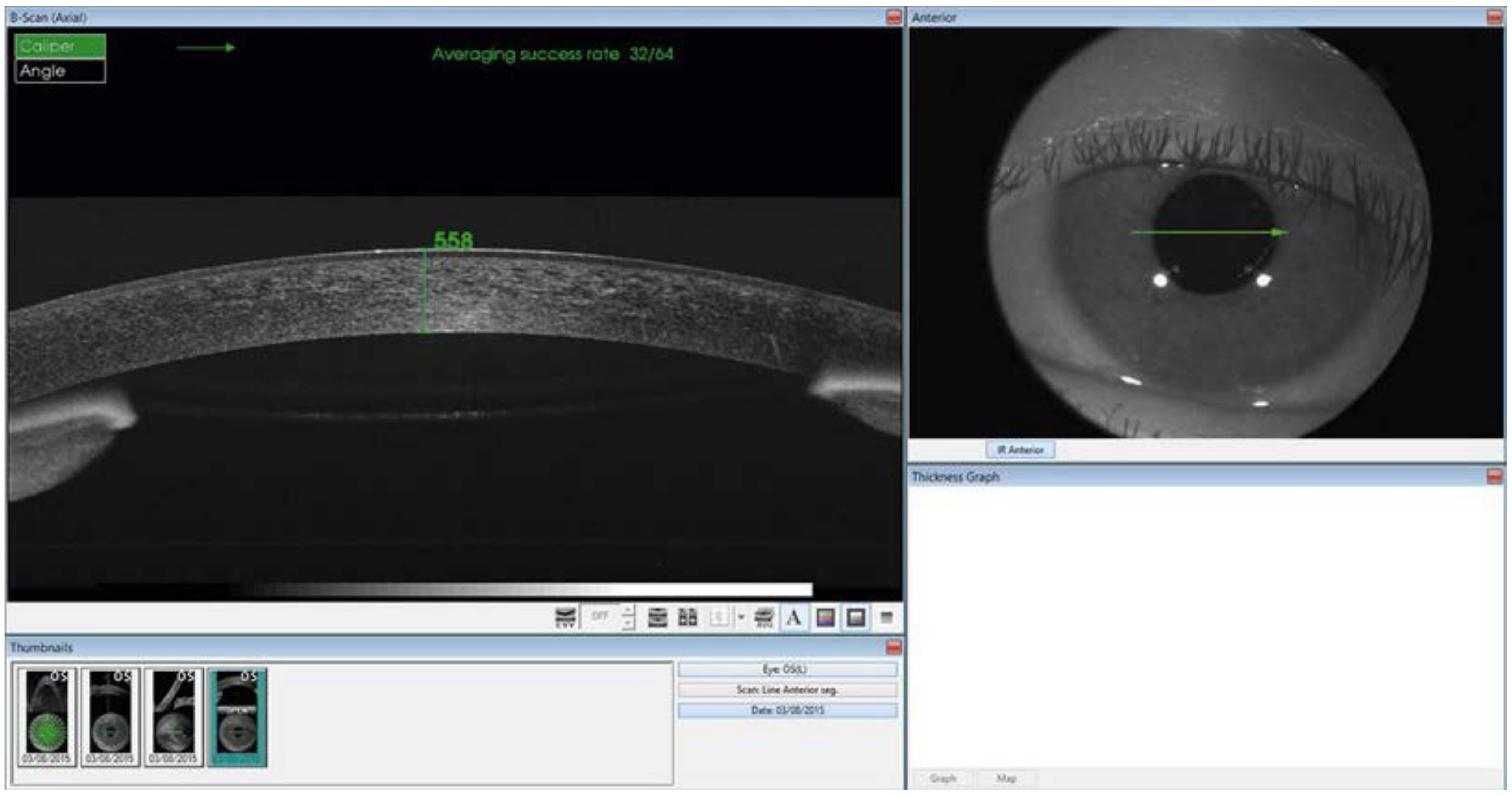


Fig. 36.28 Corneal thickness evaluation by AS-OCT. (Image courtesy of Nicholas Rumney.)

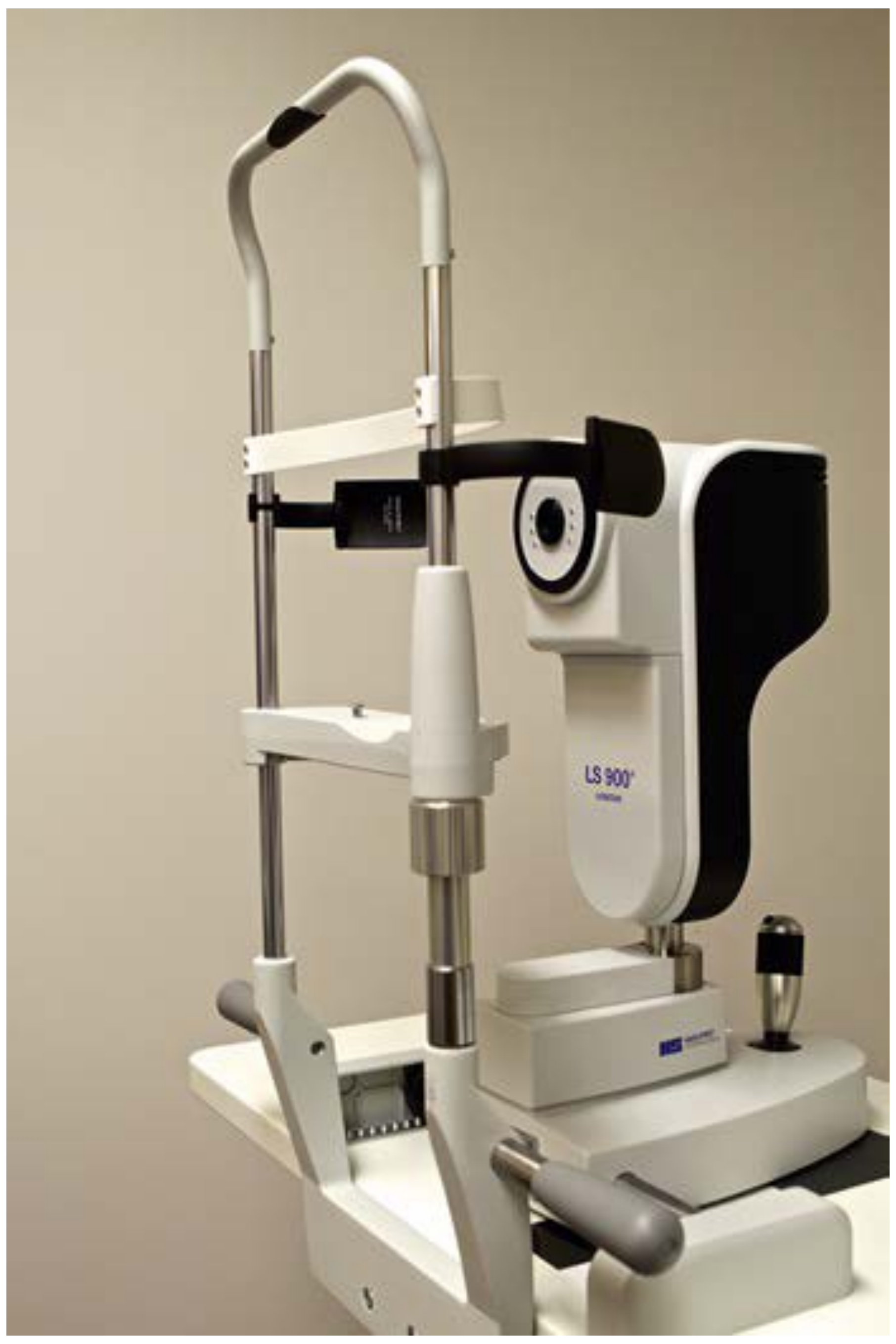


Fig. 36.29 LenStar LS 900 biometer. (Courtesy of Centre for Contact Lens Research and Haag-Streit.)

endothelial layers (Li et al., 1997). The technique can thus be used to accurately determine corneal thickness in health and disease (Javaloy et al., 2004; McLaren et al., 2004; Williams et al., 2011; Al Farhan et al., 2013; Rio-Cristobal and Martin, 2014).

SPECULAR MICROSCOPY

The contact and non-contact specular microscope is able to determine the location of the epithelium and endothelium. By determining the distance between these two corneal layers, the thickness of the cornea can be estimated (Modis et al., 2001; Zhao et al., 2007a; Hamano et al., 2008; Al-Ageel and Al-Muammar, 2009; Almubrad et al., 2011).

LENSTAR LS 900

The LenStar LS 900 (Haag-Streit AG, Koeniz, Switzerland) uses non-contact optical low-coherence reflectometry to provide a complete biometrical assessment of the patient's eye in a single measurement procedure, including keratometry, lens thickness, anterior-chamber depth (lens position), axial length and retinal thickness (Buckhurst et al., 2009). It can also provide assessment of central corneal thickness (Gursoy et al., 2011; Kolodziejczyk et al., 2011; Tai et al., 2013; Bayhan et al., 2014; Borrego-Sanz et al., 2014; Simsek et al., 2016) (Fig. 36.29).

In summary, many multifunctional devices share similar features and can determine similar physiological parameters such as corneal pachymetry. It is important to note that the values obtained are generally not interchangeable between instruments.

Conclusion

It is clear that the consulting room of the contact lens practitioner will become increasingly sophisticated as the emerging technologies described in this chapter gain increasing acceptance, leading to these instruments becoming more affordable. It is likely that the affordability is directly influenced by the reduced time taken to fit complex lenses such as semiscleral, scleral and hybrid lenses. Notwithstanding these remarkable developments, it is likely that observation of the anterior segment using the slit-lamp biomicroscope will remain the cornerstone apparatus for the investigation, even if not the measurement, of the contact-lens-wearing eye.

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Access the complete references list online at http://www.expertconsult.com.

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37

Preliminary Examination

ADRIAN S BRUCE

Introduction

The preliminary examination includes the taking of a full history and initial patient assessment (see Chapter 35), ocular measurements, refraction, slit-lamp biomicroscopy and additional tests. The examination enables the practitioner to advise patients on their suitability for contact lens wear and, if it is decided to go ahead with lens fitting, of appropriate lens choices. The information obtained from the preliminary examination is vital in the selection of the most suitable lens type (soft, corneal or scleral), replacement frequency, wear modality (daily or extended wear), care system and wearing time.

The preliminary examination also forms a baseline for the monitoring of the patient's eye condition. Possible clinical questions include:

1. Whether keratoconus is present and if cross-linking is necessary.
2. If a corneal graft is showing signs of rejection or whether the intraocular pressure is increased by steroid treatment.
3. In high myopia, whether there are peripheral retinal changes or signs of glaucoma.

This chapter provides an overview of the typical full routine of the preliminary contact lens examination, following case history, and comments on the interpretation of the information obtained. The sequence of examination described is shown in Fig. 37.1. Details of the instrumentation referred to in this chapter can be found in Chapter 36.

Measurement of Vision

After the case history, vision is usually the first measurement in the preliminary examination. The initial measurement gives the habitual vision of the patient, unaffected by later test procedures that use lights or ocular manipulations. An additional benefit of the baseline measure of vision is for medicolegal reasons.

The computer-presented visual acuity chart has advantages over other types of vision chart for contact lens practice, but in particular computer-generated optotypes can be randomized to prevent the contact lens patient from learning the letter sequences at successive visits.

Vision should be measured with and without the habitual distance spectacles of the patient at both distance and near. The level of vision will be useful information to relate to the history, refraction and the binocular vision examination. The unaided vision is of interest because patients who are commonly or intermittently uncorrected will compare that with the level of acuity they achieve with contact lenses.

Objective and Subjective Refraction

The first phase of the refraction is to undertake preliminary objective assessment. Digital autorefractors are now being used more commonly; these devices are combined in a single instrument that can also perform tonometry and/or corneal curvature assessment. A fully objective digital assessment of the optical quality of the eye requires a wavefront refraction (see later in this chapter).

The long-established, skilled art of retinoscopy still has utility in contact lens practice; as well as allowing objective determination of refractive status, it also enables the quality of optics of the eye to be assessed. Possible indications for retinoscopy include:

- vision with spectacle refraction of less than 6/6 (20/20)
- astigmatism of higher levels, or changing magnitude or direction of astigmatism, where keratoconus may be suspected

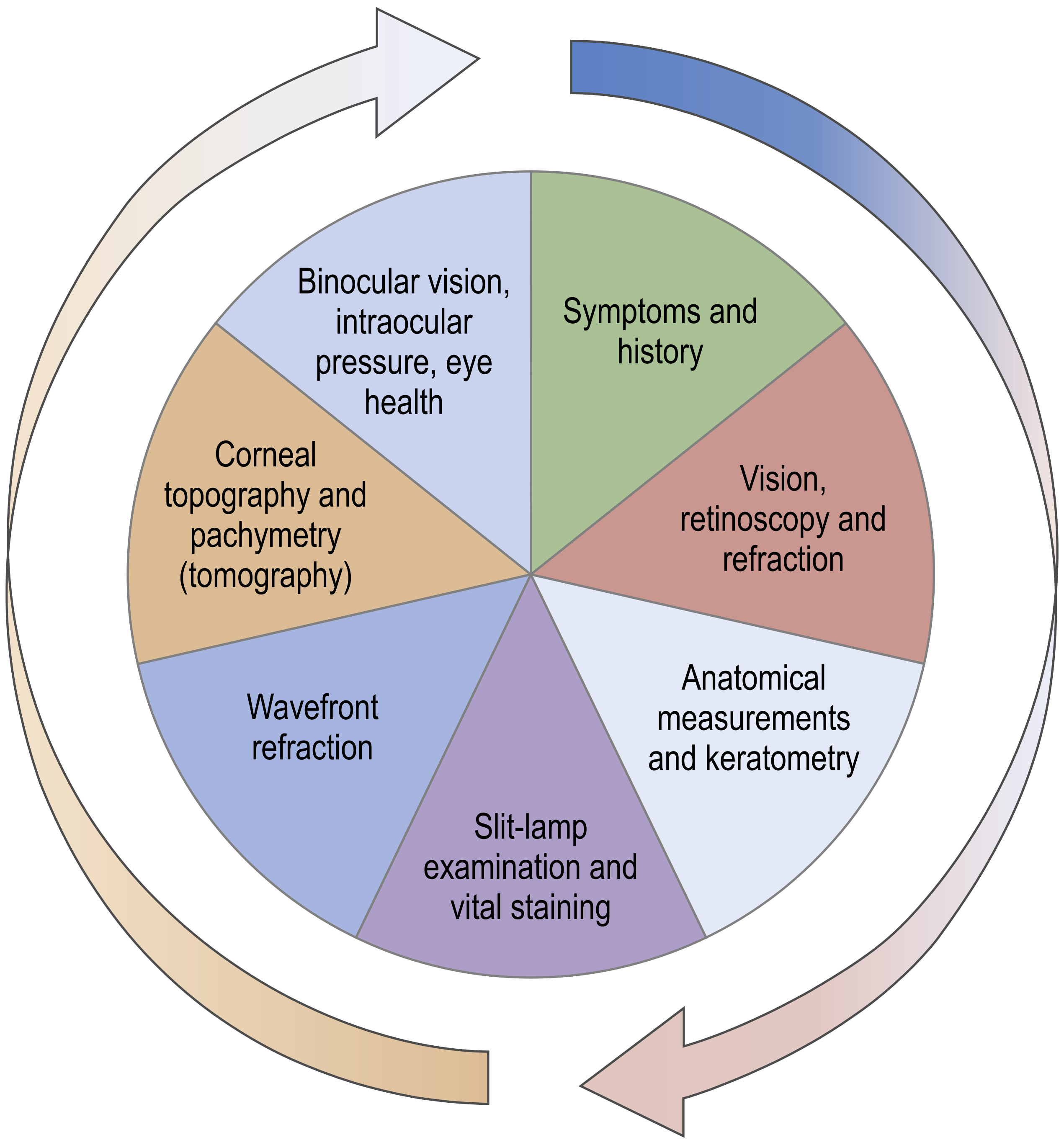

Symptoms and history
Vision, retinoscopy and refraction
Anatomical measurements and keratometry
Slit-lamp examination and vital staining
Wavefront refraction
Corneal topography and pachymetry (tomography)
Binocular vision, intraocular pressure, eye health

Fig. 37.1 Flow of the preliminary examination for contact lenses. Standard procedures are located at the top of the chart and proceed clockwise. More advanced tests such as corneal topography, wavefront refraction or corneal tomography are conducted on indication (e.g. previous diagnostic history, loss of best corrected visual acuity, scissors reflex on retinoscopy or key slit-lamp signs of corneal irregularity).

- looking for clues of corneal irregularity, such as a scissors reflex (Goebels et al., 2015)
- pseudomyopia, whereby less minus may be revealed.

The subjective refraction may be best performed in a trial frame, since many contact lens patients are young and the trial frame may be less likely to induce accommodation than the phoropter. Even if 6/6 (20/20) vision is achieved with the patient's current spectacles or contact lenses, it is useful to check the subjective refraction in each eye for excess minus power that could account for symptoms unrelated to visual acuity (such as asthenopia or binocular vision problems).

It is necessary with non-presbyopic patients to adopt a technique with the refraction so as to relax their accommodation. Measuring a blur function is one such method, whereby the addition of +0.50 D or +0.75 D lenses is expected to almost completely blur the 6/6 (20/20) line.

Anatomical Measurements

Measurements of the dimensions of anatomical structures of the anterior eye should be routinely made for contact lens fitting. Because of the differences in fitting characteristics between soft and rigid lenses, different sets of measurements may be required.

Horizontal corneal diameter is usually between 10 and 13 mm (average about 11.5 mm) (Alfonso et al., 2010). A cornea of less than 10 mm may be defined as microcornea and one greater than 13 mm as megalocornea. The cornea reaches adult dimensions by about 2 years of age.

The pupil diameter is usually between 3 and 6.5 mm under photopic conditions, and about 5–8 mm under mesopic conditions. Patients with large pupils are usually more sensitive to refractive error and even small amounts of corneal irregularity. For these patients, contact lenses with larger optical zones may be beneficial.

For rigid lens fitting, it is useful to record the upper and lower eyelid positions in relation to the cornea. Assessment of lid geometry assists in the selection of lens diameter and design for the optimization of lens comfort. Most often, the upper eyelid covers the superior limbus by 1–2 mm, and the lower eyelid is very near the inferior limbus (Bruce, 2006). An unusually high or lower eyelid positions should be noted.

Protocols for anatomical measurement when fitting soft and rigid lenses are given in Chapters 7 and 14, respectively.

Keratometry

Assessment of corneal shape is a standard part of the contact lens preliminary examination. Digital topographers that provide a detailed map of the shape of the cornea are rapidly becoming the norm in contact lens practice (see below); however, the optical keratometer can measure the curvature of the principal meridians of the central 3 mm of the cornea, known as K-readings, which are useful measures for many aspects of contact lens fitting.

For soft lens fitting, particularly disposable lenses, which might, for example, be available in only two back optic zone radii (BOZR), the assessment is often used simply to identify steeper corneas, which require the lens with the steeper (smaller) BOZR.

In rigid lens fitting the K-readings are used directly to select the BOZR of the initial trial lens. The amount of keratometric astigmatism should be compared with the ocular astigmatism. This identifies lenticular astigmatism, which may be the cause of residual astigmatism in rigid lens wear. If the keratometry mires appear distorted, then irregular astigmatism may be present, i.e. where the principal axes are not orthogonal.

Keratometry is a simple, rapid and non-invasive test, but it does have some limitations. It measures only central corneal radius, it assumes a spherical cornea with regular astigmatism and it has a limited range of powers (36.00–53.00 D). Extreme corneal powers can be measured by interposing a −1.00 D lens (for low corneal powers, i.e. very flat corneas) or a +1.25 D lens (for high corneal powers, i.e. very steep corneas) in front of the keratometer. The keratometer reading is converted to the actual corneal power using tables (Appendix E).

As well as the keratometer, K-readings may also be obtained from many autorefractors, as well as with corneal topography and tomography (see later in this chapter).

Slit-lamp Biomicroscopy

In the preliminary examination, biomicroscopy is used to assess the health of the anterior eye, and to identify conditions or features that may be relevant to contact lens wear. It is also important to record baseline appearance of the eyes for medicolegal reasons.

Six areas of the anterior eye should be assessed in the preliminary examination, and any signs should be reconciled with symptoms and assessment of the corneal curvature (Fig. 37.2).

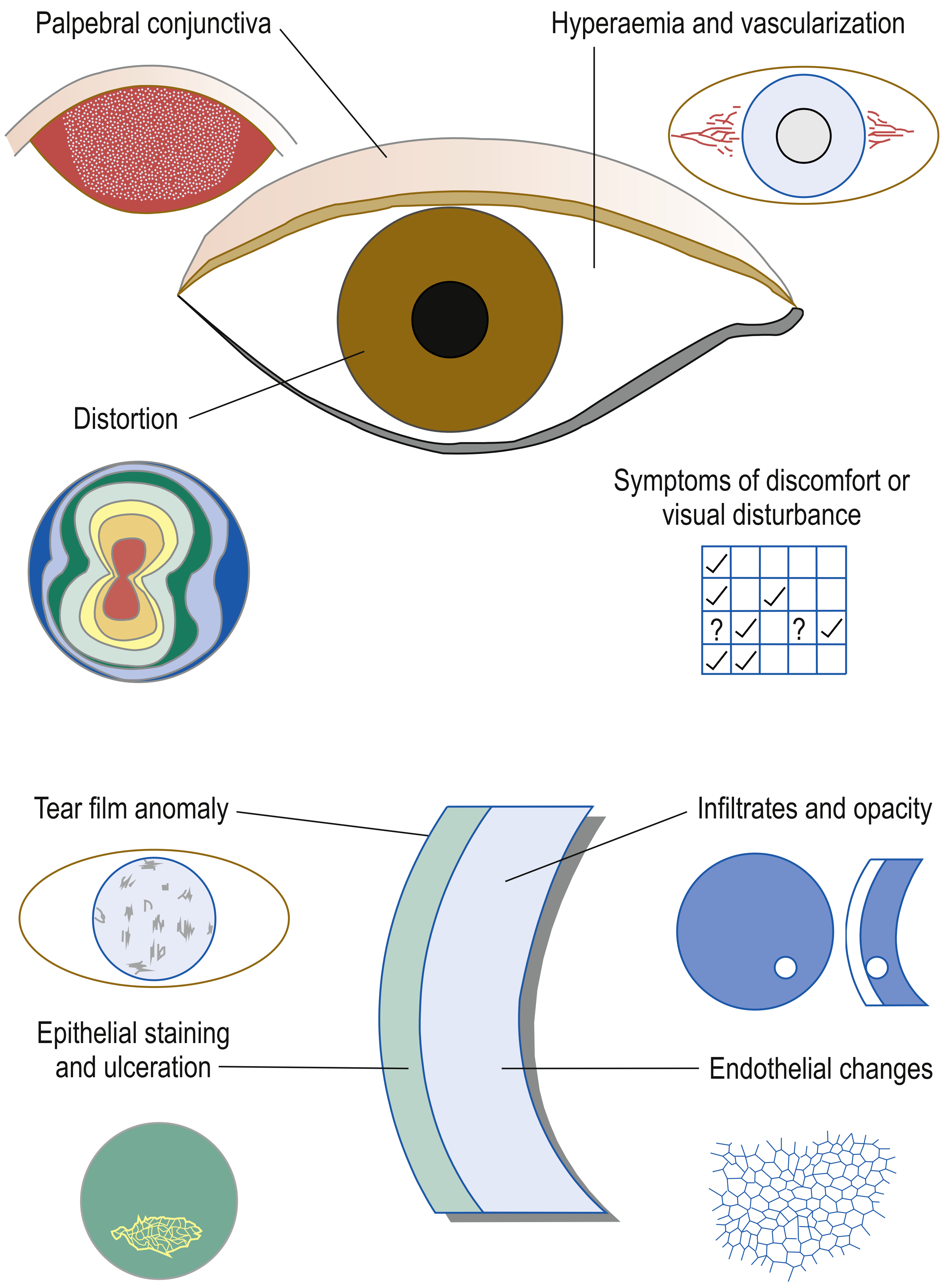

Palpebral conjunctiva
Hyperaemia and vascularization
Distortion
Symptoms of discomfort or visual disturbance
Tear film anomaly
Infiltrates and opacity
Epithelial staining and ulceration
Endothelial changes

Fig. 37.2 Considerations in the assessment of the anterior eye. There are six primary areas to examine with the slit lamp, as well as considering corneal shape and symptoms. (Adapted from Bruce, A. S. & Brennan, N. A. (2000). A Guide to Clinical Contact Lens Management, 3rd ed. Duluth, GA: CIBA Vision.)

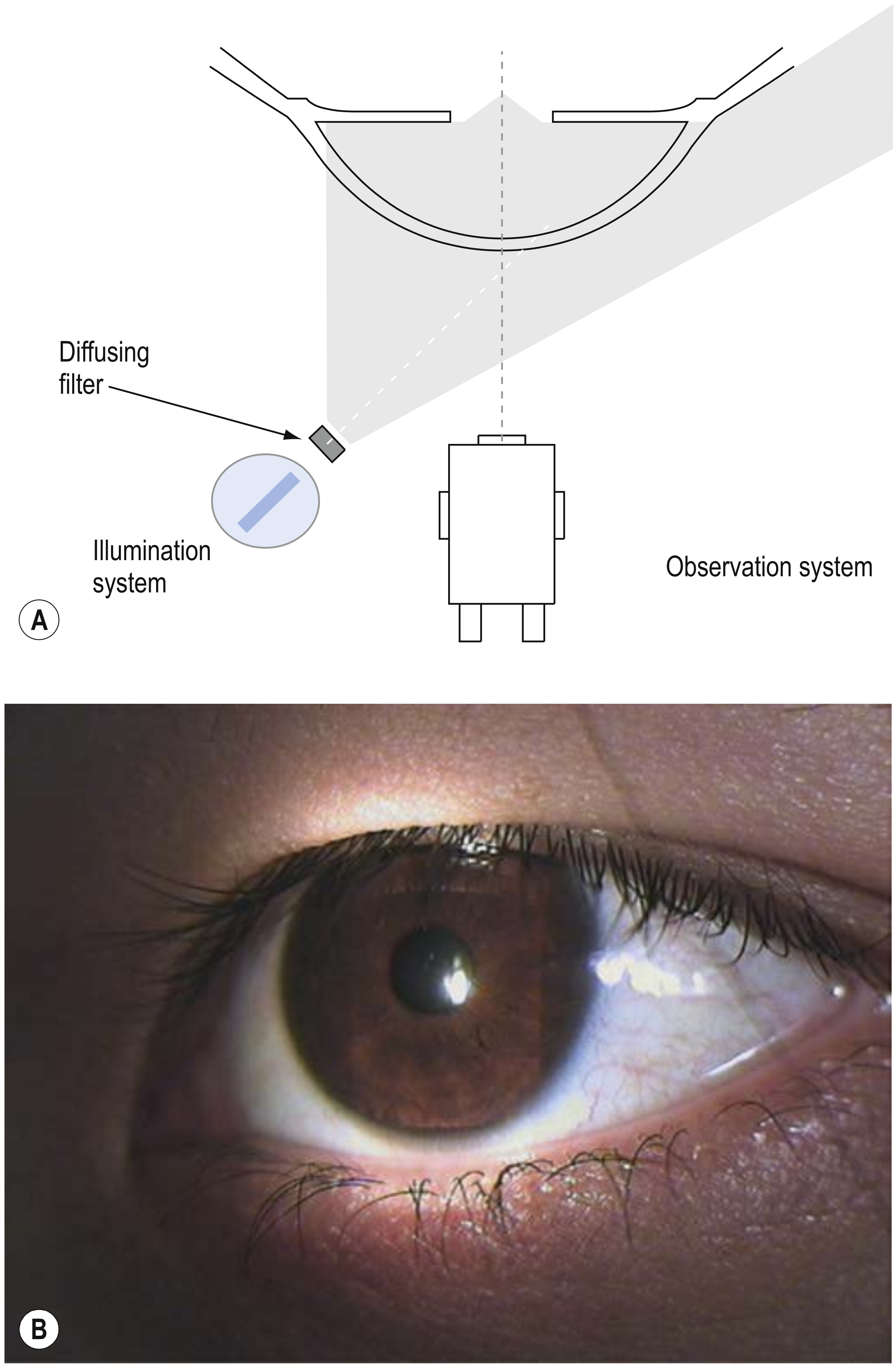


Fig. 37.3 (A) Diffuse illumination slit-lamp technique. (B) Diffuse illumination view of the cornea. ((A) Adapted from Jones, L. W. & Jones, D. A. (2001). Slit lamp biomicroscopy. In N. Efron (ed.) The Cornea: its Examination in Contact Lens Practice (pp. 1–49). Oxford: Butterworth-Heinemann.)

Characteristics of the normal anterior eye, and the severity of any abnormalities that are detected, can be recorded with the assistance of grading scales (see Chapter 39). Efron and McCubbin (2007) have demonstrated that effective grading can be undertaken in a few seconds, which means that this important clinical practice will not consume undue amounts of valuable chair time.

A normal technique is to use a variety of illumination methods – such as those described below (Jones and Jones, 2001) – and cobalt blue light for fluorescein staining.

DIFFUSE WIDE BEAM

A diffuse wide beam is generally used to provide low-magnification views of the opaque tissues of the anterior segment, including the bulbar conjunctiva, sclera, iris, eyelid margins and the tarsal conjunctiva of the everted eyelids (Fig. 37.3).

A broad, even illumination over the entire field of view may be produced in a variety of ways. Some slit lamps may have a ground-glass filter placed to diffuse the focused light beam of the slit lamp, others may have a separate fibre optic for background illumination, otherwise the slit-beam intensity is reduced and opened to full width.

Unusual clinical signs could involve the bulbar conjunctiva vasculature, pigmented lesions in the conjunctiva or eyelids, roughness or opacity of the conjunctiva and abnormal eyelash position or orientation. Such signs could be indicative of conditions such as trichiasis, bulbar injection, pterygium or papillary conjunctivitis.

In assessing the eyelid margins, consider the apposition of the lids and puncta against the globe. Also look for clear glands near the base of the lashes, and flaking or scaling of the eyelid skin. These may indicate the presence of ectropion, blepharitis or epiphora.

DIRECT FOCAL ILLUMINATION

This describes any illumination technique where the slit beam and viewing system are focused at the same location. The illumination beam is placed at an angle of 30–50° on the side of the microscope corresponding to the section of the cornea to be viewed. This technique is most commonly used for assessing the transparent tissues of the eye (i.e. the cornea and crystalline lens) because the oblique illumination of the tissue creates a dark background for maximum contrast. Typically a beam width of 2–3 mm is chosen initially and this may be reduced so as to bring more contrast (due to less light scatter) to an area of interest.

Several specific types of direct illumination are possible, including parallelepiped, optic section and specular reflection.

Parallelepiped

Using the set-up described above, a 0.1–1.0 mm wide illuminating beam is swept smoothly over the ocular surface (Fig. 37.4), particularly to assess the ocular media (i.e. the cornea and crystalline lens). The parallelepiped is the most commonly used direct illumination technique and is employed, for example, to assess corneal scarring, infiltrates and corneal staining. The corneal profile may show signs of ectasia, thinning or asymmetry. Whilst scanning the external ocular surface, a low-to-medium magnification is initially chosen and the magnification is increased if any area of interest needs to be examined more closely.

Optic Section

Once an area or object of interest is located the beam width is narrowed to approximately 0.02–0.1 mm to take a cross-section of the corneal tissue. This provides the ability to assess accurately the location and depth of a lesion within the transparent tissue layers (Fig. 37.5). Typical uses include assessment of the depth of a foreign body, location of a corneal scar and determining whether tissue within an area of staining is excavated, flat or raised.

Specular Reflection

This is a specific case of a parallelepiped set-up, where the angle of the incident slit beam is equal to the angle of the observation axis through one of the oculars. At this angle (typically 30–50°) the illumination beam is reflected from the smooth optical surfaces of the anterior segment and provides a mirror-like reflection (Fig. 37.6).

Such specular images occur at every interface between tissues of different refractive index. At the corneal endothelium, the technique may reveal changes such as endothelial blebs,

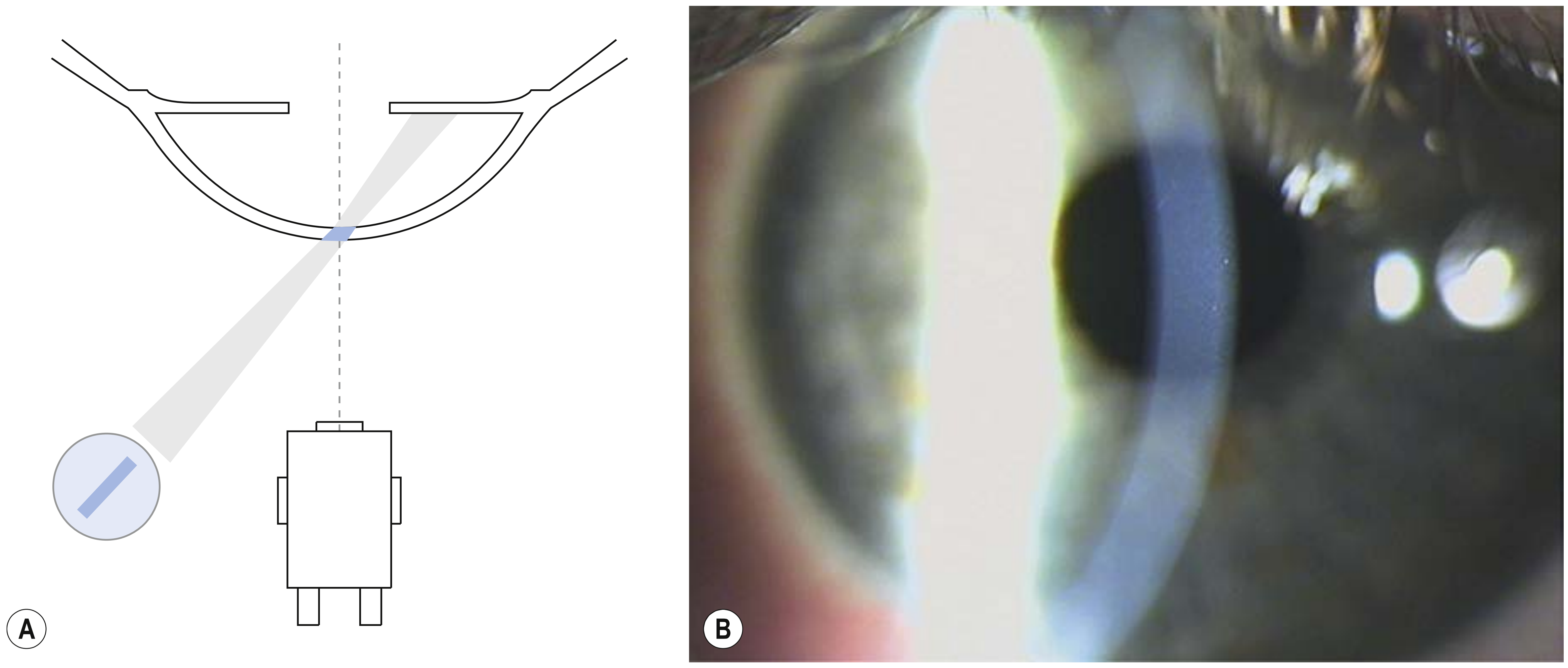


Fig. 37.4 (A) Parallelepiped slit-lamp technique. (B) Parallelepiped illumination view of the cornea. ((A) Adapted from Jones, L. W. & Jones, D. A. (2001). Slit lamp biomicroscopy. In N. Efron (ed.) The Cornea: its Examination in Contact Lens Practice (pp. 1–49). Oxford: Butterworth-Heinemann.)

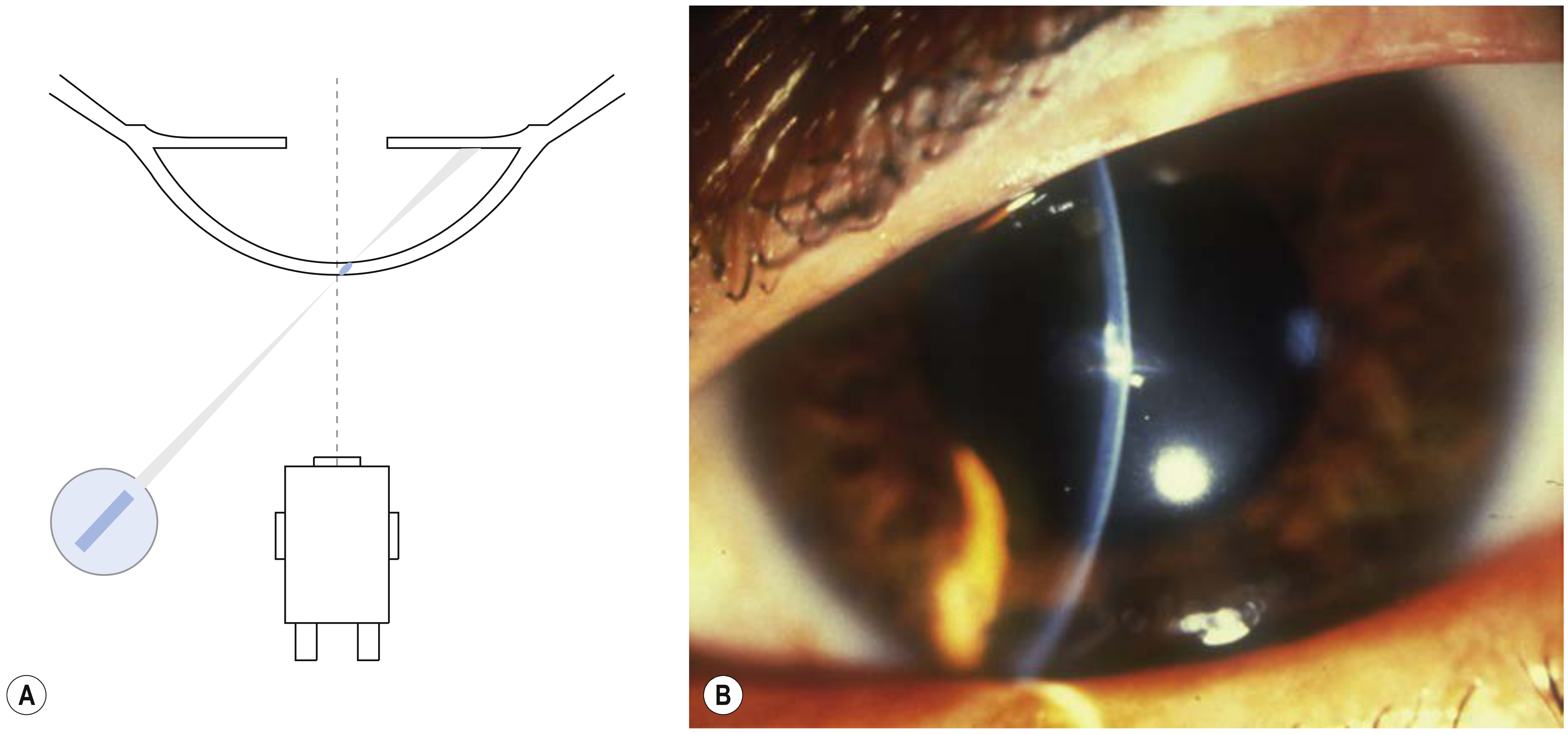


Fig. 37.5 (A) Optic section slit-lamp technique. (B) Optic section view of a corneal foreign-body injury. ((A) Adapted from Jones, L. W. & Jones, D. A. (2001). Slit lamp biomicroscopy. In N. Efron (ed.) The Cornea: its Examination in Contact Lens Practice (pp. 1–49). Butterworth-Heinemann. (B) Courtesy of Pablo Gili Manzanaro, Bausch & Lomb Slide Library.)

guttae and polymegethism. The tear film lipid layer and the inferior tear meniscus can also be readily examined, as well as the anterior surface of the crystalline lens. If a contact lens is being worn, front-surface wetting break-up time can be assessed and the post-lens tear film status may be evaluated (Little and Bruce, 1994; Hom and Bruce, 2009).

INDIRECT ILLUMINATION

This refers to any technique where the focus of the illuminating beam is lateral or adjacent to the focal point of the observation system, although in the same plane. Indirect illumination techniques are required because light back-scattered from the ocular media (such as observed with direct illumination) often differs from the light forward-scattered or side-scattered by the same tissues. Evaluation of the ocular media using indirect illumination is more likely to provide information on the visual effect for the patient (Pinero et al., 2010).

Two specific types of indirect illumination are possible: retroillumination and sclerotic scatter.

Retroillumination

This refers to the technique of directing light onto the iris, anterior lens surface or fundus, in order to back-illuminate the cornea or crystalline lens. The angle of the incident slit beam to the observation axis through one of the oculars is usually small (10–20°) if the fundus is being used, but the angle may be greater if the iris is used. By lateral movement of the slit beam in the same focal plane, the lesion or area of transparent tissue may be examined.

The area of interest may be seen against a light background (direct retroillumination; Fig. 37.7) or a dark background (indirect retroillumination; Fig. 37.8), depending on whether or not the illumination and viewing systems are coincident. Direct retroillumination is used most often, whereby corneal or lenticular opacities will appear dark against a bright field. This technique

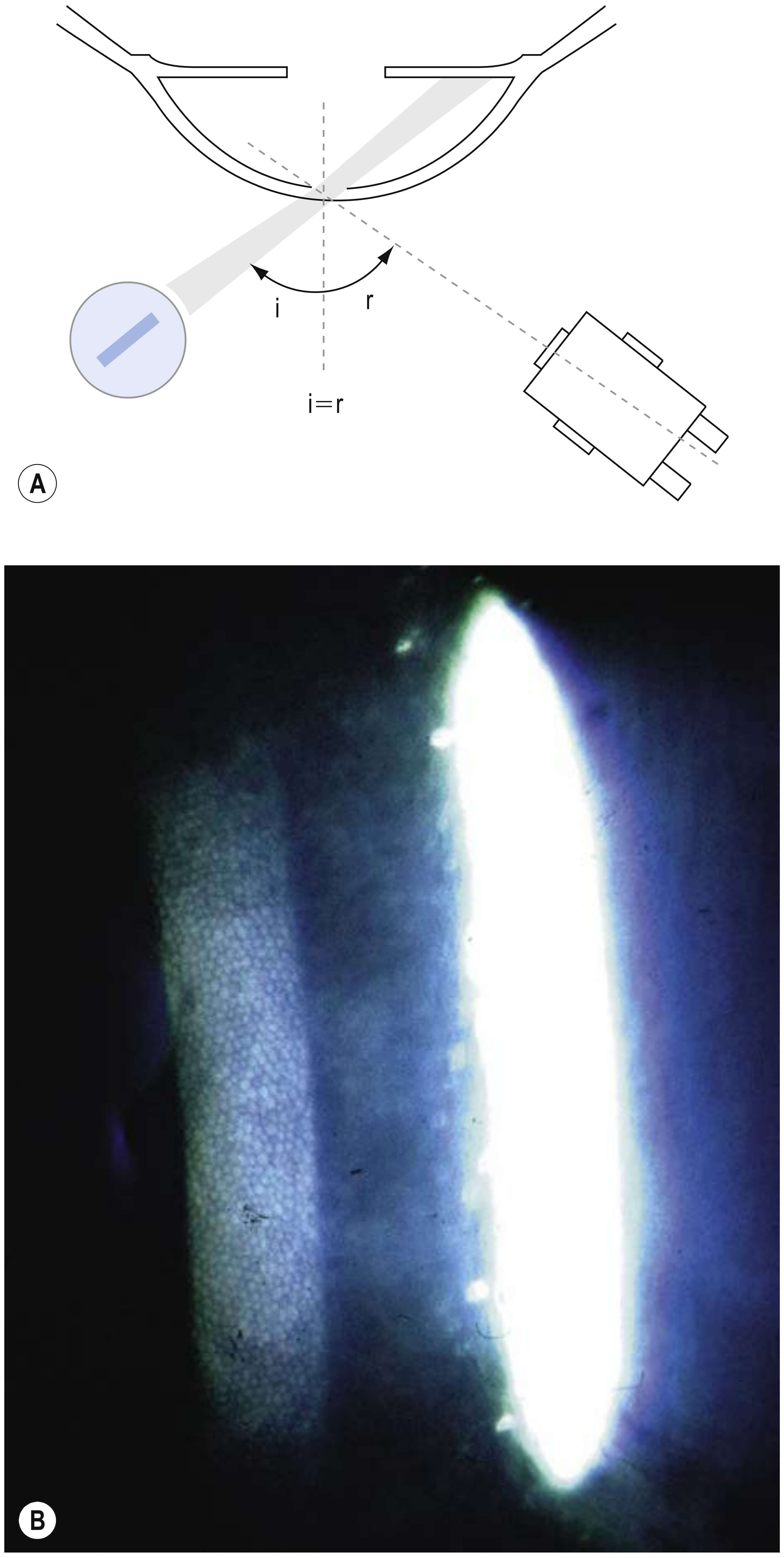


Fig. 37.6 (A) Specular reflection slit-lamp technique. (B) Specular reflection view of the corneal endothelium. i = angle of incidence; r = angle of reflection. ((A) Adapted from Jones, L. W. & Jones, D. A. (2001). Slit lamp biomicroscopy. In N. Efron (ed.) The Cornea: its Examination in Contact Lens Practice (pp. 1–49). Oxford: Butterworth-Heinemann.)

is particularly useful for examining epithelial microcysts, neovascularization, scars, corneal degenerations, iridectomy, pigmentary dispersion and cataract.

Sclerotic Scatter

This technique is used to investigate any subtle changes in corneal clarity occurring over a large area, such as central corneal oedema. The slit lamp is set up for a wide-angle parallelepiped (45–60°) and the viewing system is focused centrally. The beam is manually offset ('uncoupled') and focused on the limbus. The slit beam is totally internally reflected across the cornea and a bright limbal glow is seen around the entire cornea (Fig. 37.9).

Any specific area of abnormality, such as a corneal scar, will interrupt the beam in its passage and produce a light reflection in the otherwise-dark cornea.

FLUORESCEIN STAINING

Slit-lamp examination using the vital stain fluorescein, observed in cobalt blue light and a yellow Wratten or Boston observation filter, allows the assessment of ocular surface defects and irregularities. The cornea, bulbar conjunctiva and tarsal conjunctiva may be assessed. Tarsal papillae and roughness, as well as a wide variety of corneal changes, such as desiccation, may be detected.

Tear Film Evaluation

There are six clinical categories of technique for diagnosis of tear film impairment (the six Ss) (Mainstone et al., 1996):

1. Symptoms and history – quantify with the dry-eye survey, such as that shown in Appendix J.
2. Slit-lamp biomicroscopy – including tear meniscus height assessment and lipid layer interferometry in specular reflection.
3. Tear stability tests – most notably fluorescein or non-invasive break-up time. If contact lenses are being worn, tear stability may be assessed using the specular reflection of the slit-lamp beam, or using the mires of the keratometer or topographer (Bruce et al., 2001; Hom and Bruce, 2009).
4. Ocular staining evaluation – in particular using fluorescein or lissamine green.
5. Lid surfacing assessment – including blink rate and completeness.
6. Tests of tear secretion or quantity – such as the Schirmer and more recently the cotton thread tests (Zone Quick, Menicon).

A thorough analysis of symptoms and related history is perhaps the most important of the above tests, followed by differentiation of the type of dry eye – it often being an aqueous deficiency (with reduced tear secretion) or a meibomian gland dysfunction (with coloured lipid layer patterns in specular reflection).

Wavefront Refraction

If a patient does not achieve 6/6 (20/20) visual acuity with the subjective refraction in the preliminary examination, then an assessment of the wavefront refraction may be helpful. A wavefront refractor (aberrometer) applies a form of high-resolution autorefraction across the entire area of the patient's pupil, giving the wavefront error (WFE) in terms of micrometres of deviation (root mean square [RMS]) from the ideal wavefront plane. The irregular portion of the WFE is termed higher-order wavefront error (HO-WFE) – that is, not correctable with a standard sphero-cylindrical refraction. In the normal eye, the HO-WFE is usually less than 0.5μm (Bruce and Catania, 2014). The HO-WFE is clearly abnormal if in excess of 1.0 μm, such as in ocular pathologies affecting the cornea or crystalline lens, or following eye surgery. Abnormal ocular conditions such as keratoconus can induce a large HO-WFE, often in excess of 3.0 μm, which is particularly attributed to coma (Fig. 37.10). Wavefront refraction enables a more complete measurement of the patient's vision.

Corneal Topography

Corneal topography projects a set of illuminated concentric rings (Placido disc) onto the cornea, enabling most of the corneal surface to be measured. Especially in the assessment of

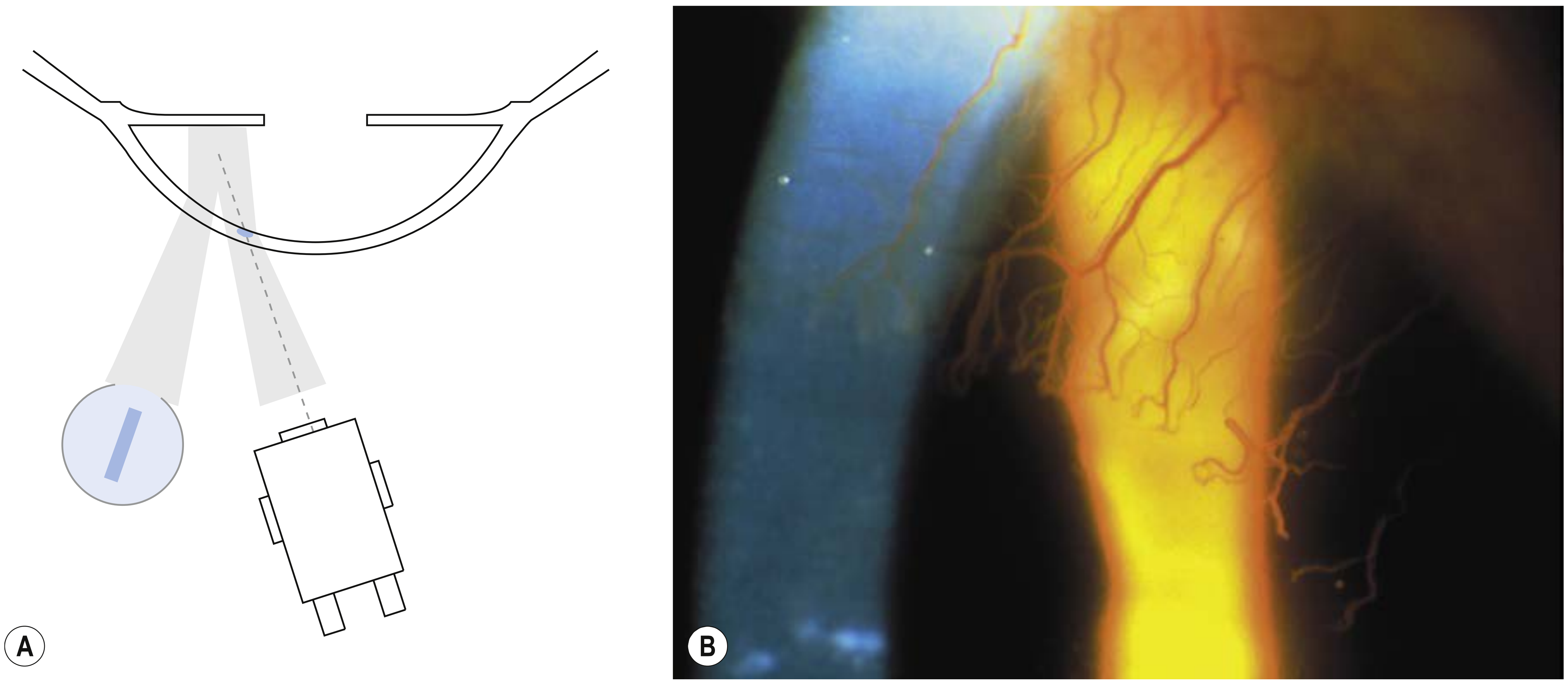


Fig. 37.7 (A) Direct retroillumination slit-lamp technique. (B) Vessels viewed by direct retroillumination against the bright iris in the background. ((A) Adapted from Jones, L. W. & Jones, D. A. (2001). Slit lamp biomicroscopy. In N. Efron (ed.) The Cornea: its Examination in Contact Lens Practice (pp. 1–49). Oxford: Butterworth-Heinemann. (B) Courtesy of Patrick Caroline, Bausch & Lomb Slide Library.)

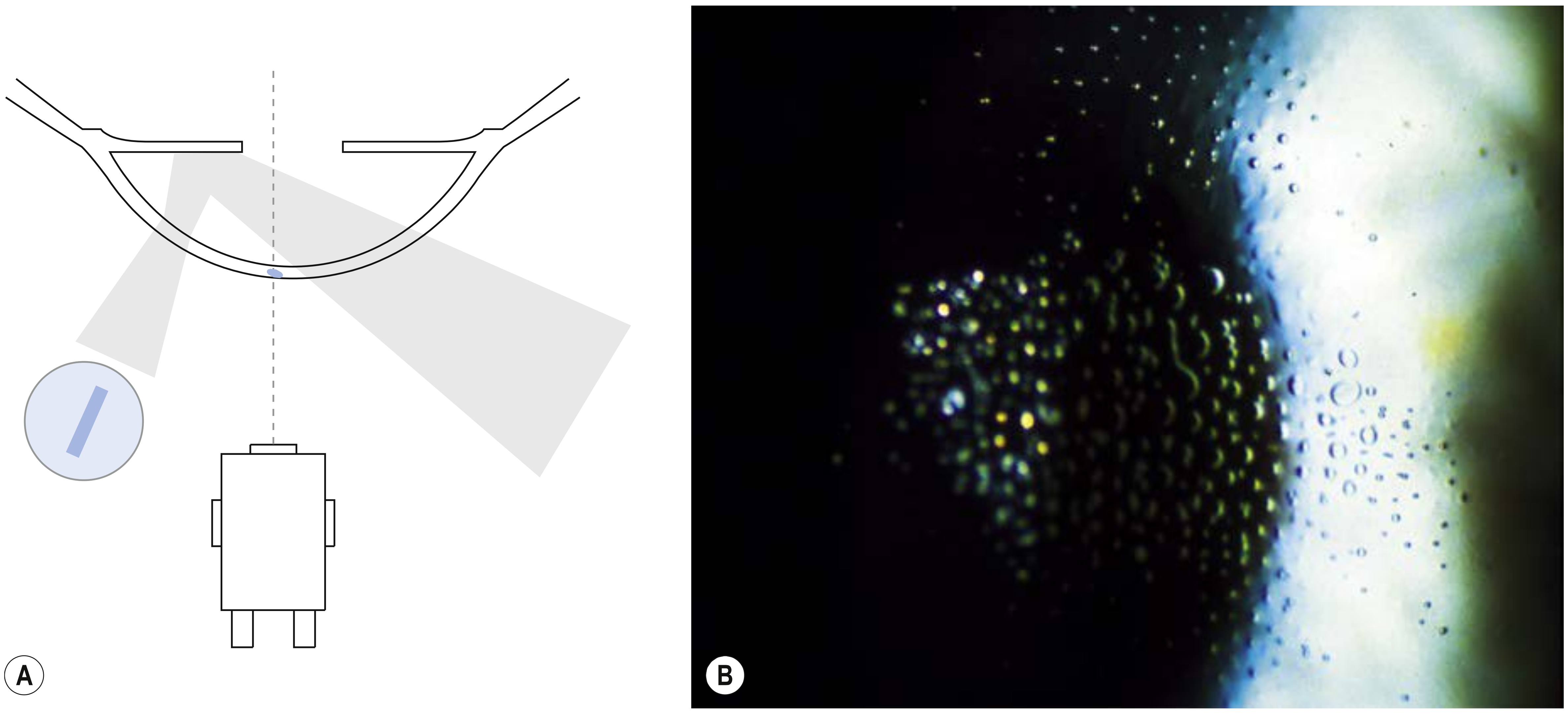


Fig. 37.8 (A) Indirect retroillumination slit-lamp technique. (B) Dimple veiling viewed by indirect retroillumination against the dark pupil in the background. ((A) Adapted from Jones, L. W. & Jones, D. A. (2001). Slit lamp biomicroscopy. In N. Efron (ed.) The Cornea: its Examination in Contact Lens Practice (pp. 1–49). Oxford: Butterworth-Heinemann. (B) Courtesy of Sylvie Sulaiman, Bausch & Lomb Slide Library.)

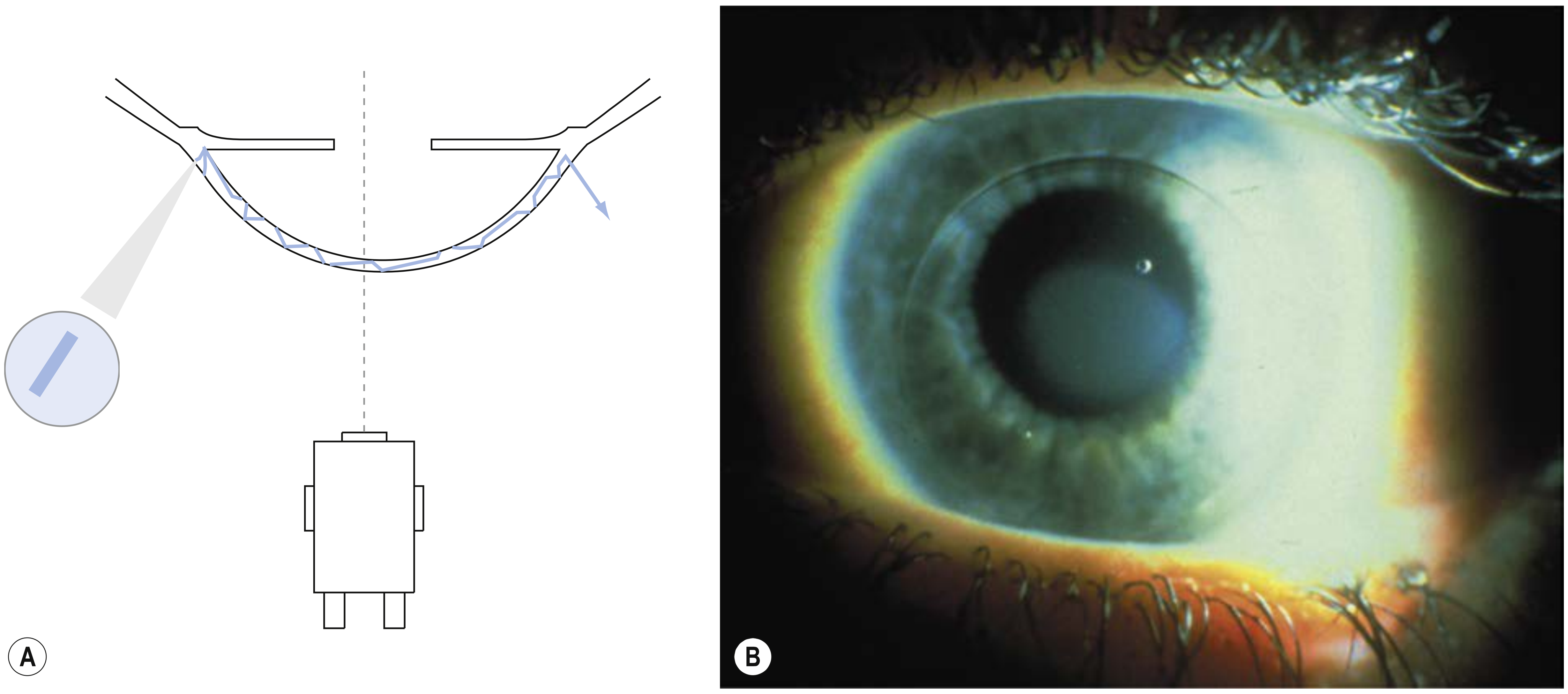


Fig. 37.9 (A) Sclerotic scatter slit-lamp technique. (B) Central corneal oedema viewed using sclerotic scatter. ((A) Adapted from Jones, L. W. & Jones, D. A. (2001). Slit lamp biomicroscopy. In N. Efron (ed.) The Cornea: its Examination in Contact Lens Practice (pp. 1–49). Oxford: Butterworth-Heinemann. (B) Courtesy of Patrick Caroline, Bausch & Lomb Slide Library.)

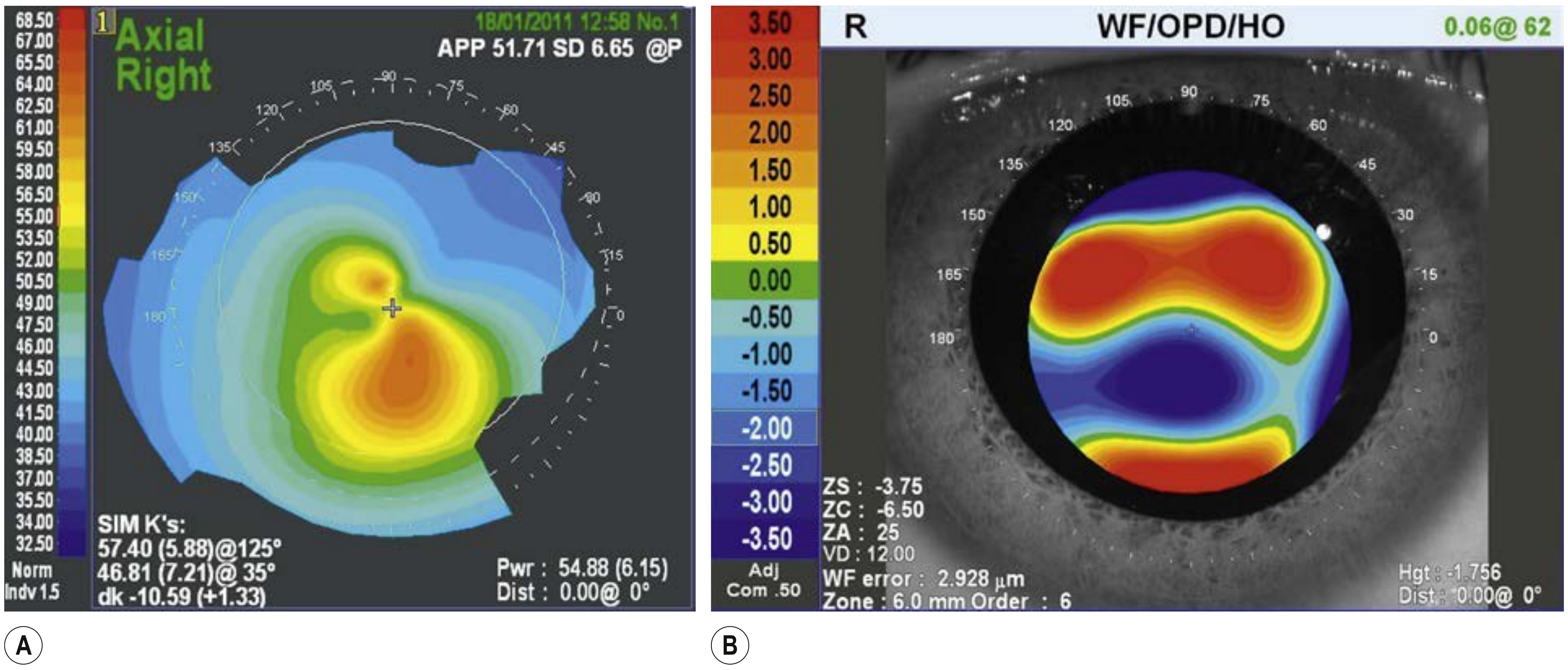


Fig. 37.10 Keratoconus in the right eye of a 20-year-old man. (A) Corneal topography map showing an apical power of 65 D. (B) HO-WFE map for a 6 mm pupil, with total higher order of 2.928 µm; total coma 2.087 µm; (Adapted from Bruce, A. S. & Catania, L. J. (2014). Clinical applications of wavefront refraction. Optom Vis Sci., 91, 1278–1286.)

conditions such as keratoconus or after surgery, it is preferable to use corneal topography in order to gain a comprehensive appreciation of the shape of the cornea (see Chapter 36).

With corneal topography, keratoconus is indicated if one or more of the following observations are found:

- a difference in corneal power of ≥1.50 D at locations 3 mm above and below the visual axis
- an apical corneal power ≥47.00 D
- interocular asymmetry in apical corneal power ≥1.00 D (Bruce and Bohl, 1992).

Corneal topography maps may be displayed in a number of ways. The most common format is known as the axial (sagittal) map, where all curvatures are calculated in reference to the visual axis of the patient. Axial maps are useful in the diagnosis of a range of corneal conditions (Fig. 37.11).

A tangential (instantaneous) map provides a more accurate guide to corneal topography. Tangential maps are based on local curvature at each corneal point and more sensitive for detecting localized changes (e.g. keratoconus, postsurgical). In addition, tangential maps show the true position of the corneal apex and will correspond to a rigid lens fluorescein pattern.

Corneal Tomography and Pachymetric Mapping

Corneal tomography is a three-dimensional reconstruction of the cornea, including anterior and posterior surface elevation analysis, pachymetric mapping and anterior corneal topography. Corneal tomography gives the most comprehensive assessment for ocular pathologies affecting the cornea or following eye surgery. Most instruments also allow anterior chamber assessment for glaucoma and the Scheimpflug-based instruments can image the crystalline lens.

Corneal tomography results are typically presented in a 'Quad-map' format, with a particular emphasis on the elevation and pachymetry data, but also including an axial (sagittal) or refractive curvature map for reference (Fig. 37.12). By showing the different analyses together, it is possible to understand the entire three-dimensional reconstruction of the cornea. In order to make it easier for the clinician to understand corneal elevation data, both the anterior and posterior corneal surface elevation data are presented in comparison to a reference shape, usually a best-fit sphere (Belin and Khachikian, 2010). The anterior elevation map and the best-fit sphere data are also available on many Placido topographers and can be used as a guide for rigid lens fitting.

Ophthalmoscopy

An ocular fundus exam is a routine part of an initial patient examination for screening ocular disease. Examination of the ocular media in retroillumination with a +10.00 D lens addition to the ophthalmoscope also shows cataract or corneal abnormalities.

A mydriatic fundus examination is often beneficial, enabling assessment of the optic disc with stereopsis and visualization of the retinal periphery. Mydriasis may also be used if there is a reduction in visual acuity, or symptoms of flashes or floaters, among other indications.

Binocular Vision Assessment

Contact lens wear may exacerbate the effect of a pre-existing accommodation or convergence insufficiency; the optical basis for this is explained in Chapter 3. In essence, there may be differences in vergence and accommodation demand between contact lenses and spectacles. In higher degrees of myopia, the contact lenses can require greater accommodation and convergence by the wearer for near activities. Depending upon age, the patient may also need to be advised that a near correction is required at an earlier age.

If the patient has pre-existing symptoms of difficulty with near vision, then accommodation and vergence performance should be assessed. Measures should be compared with age norms for accommodative amplitude, near point of convergence, distance and near heterophoria, relative near accommodation and vergence reserves at near.

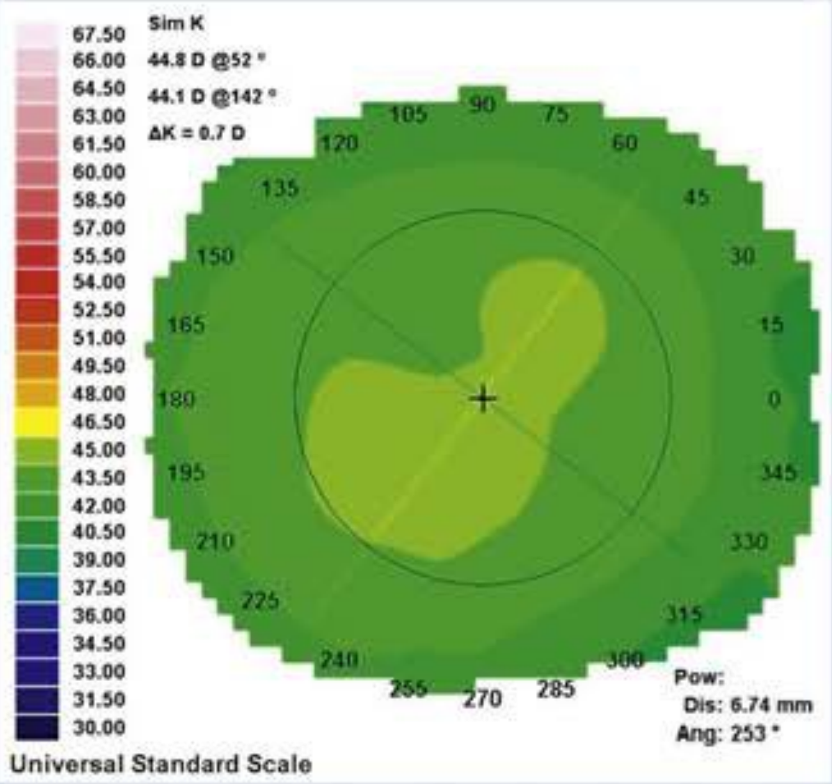
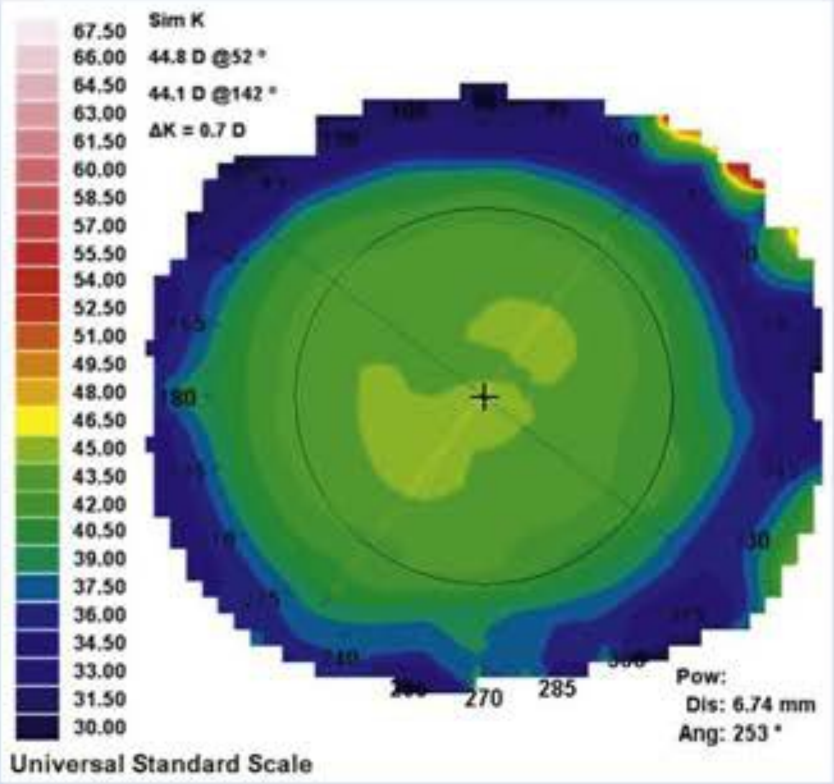
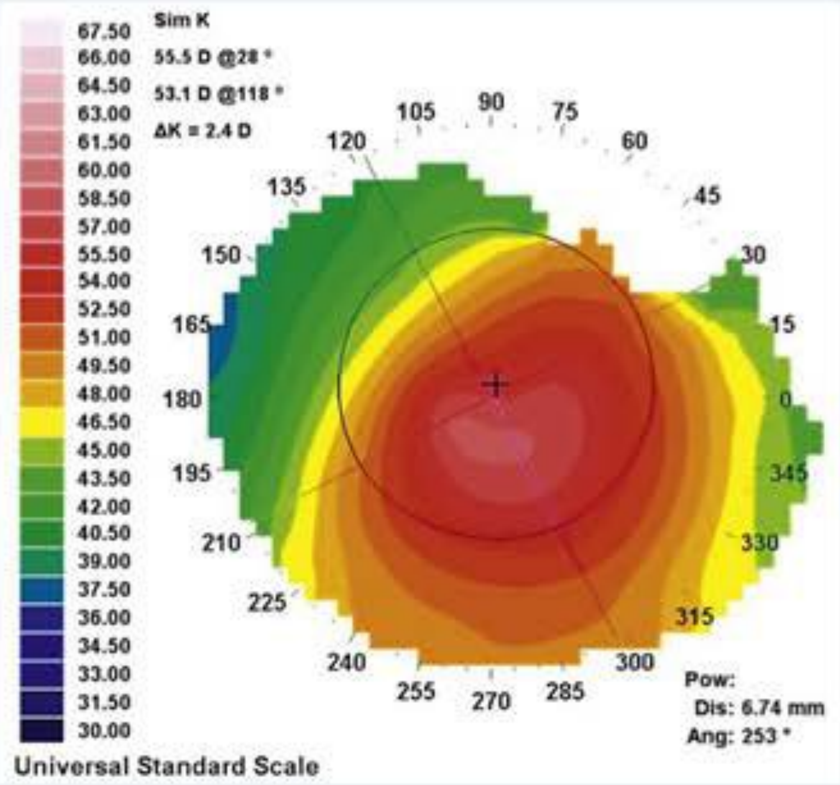
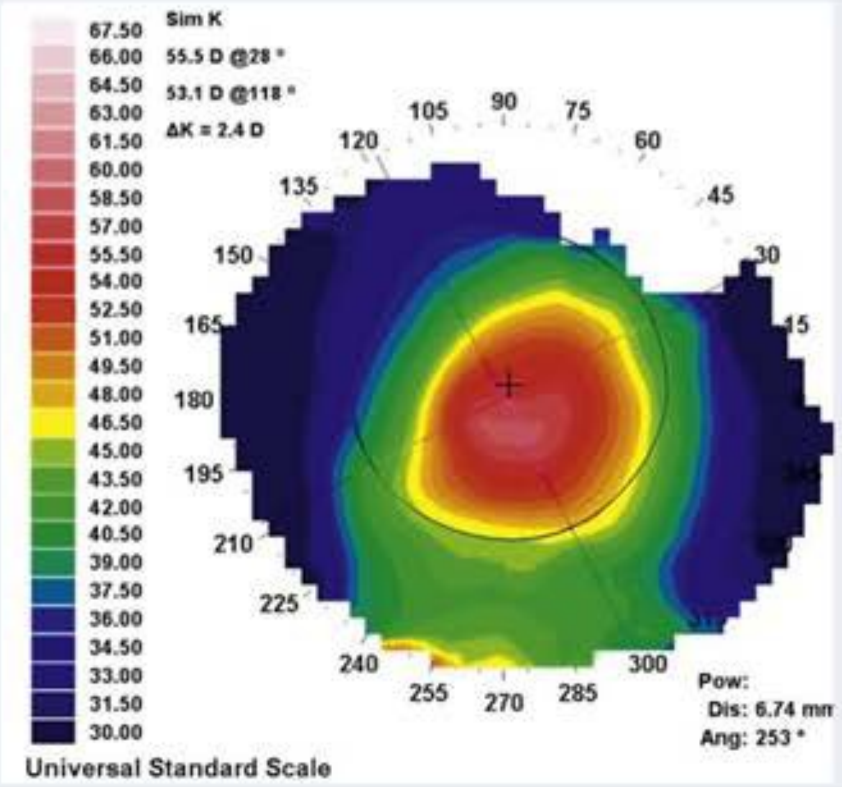
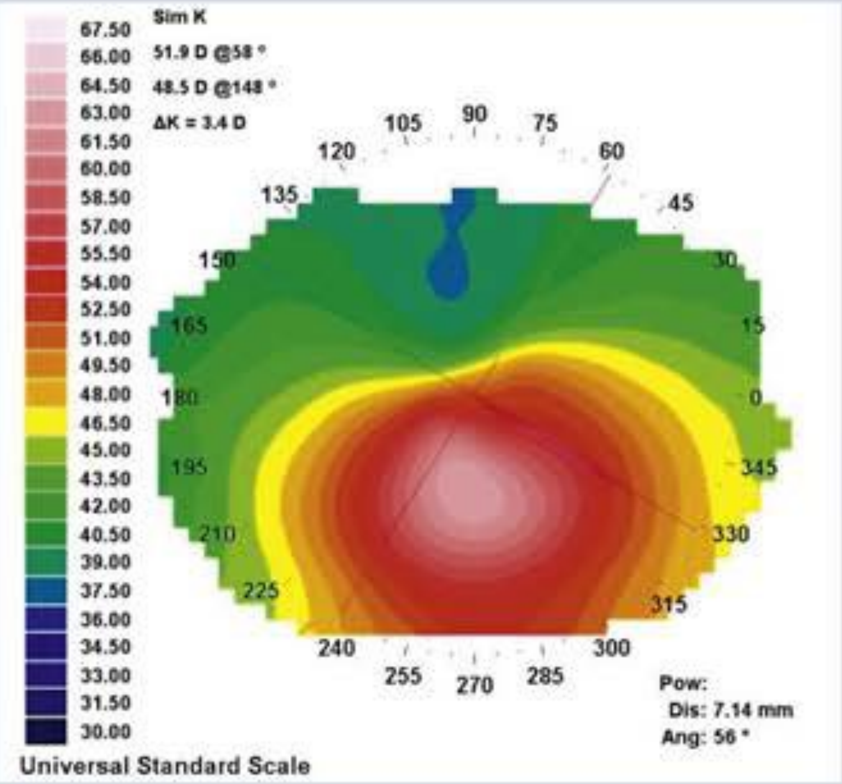
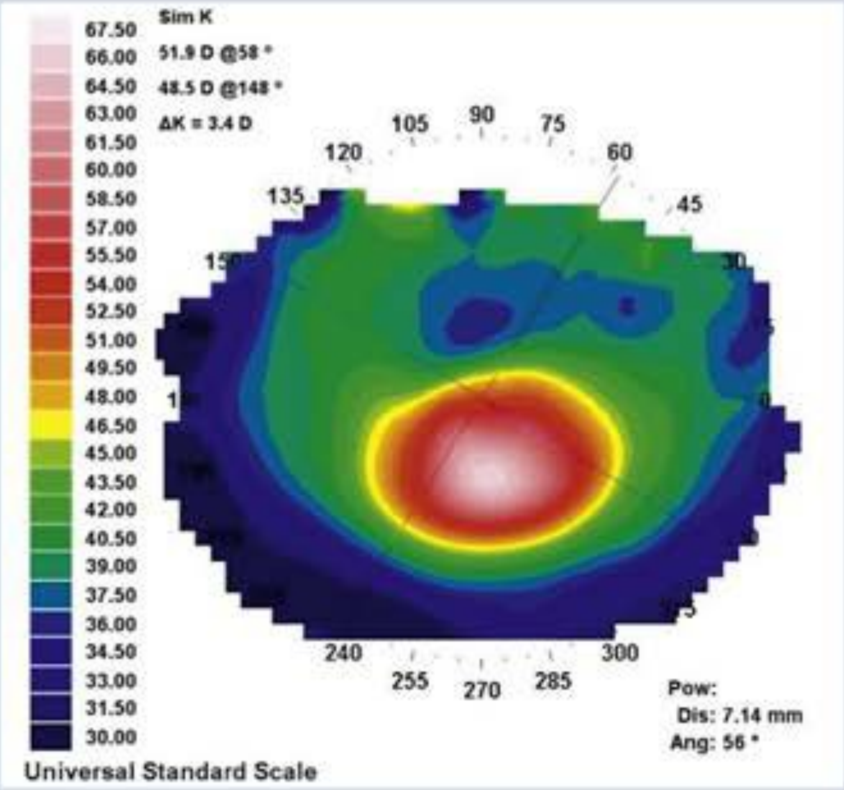
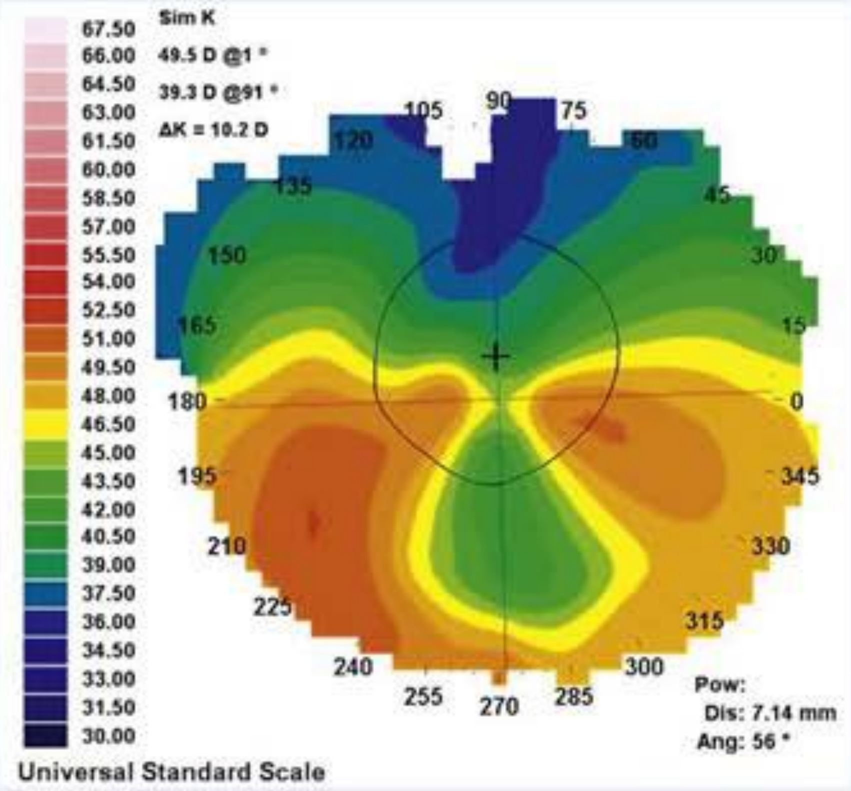
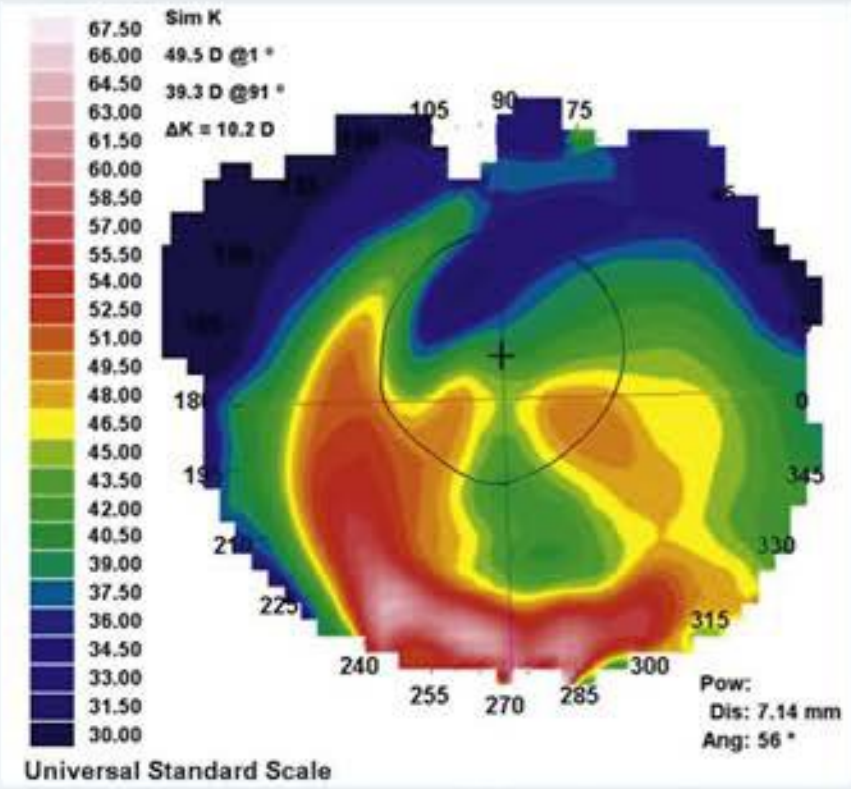
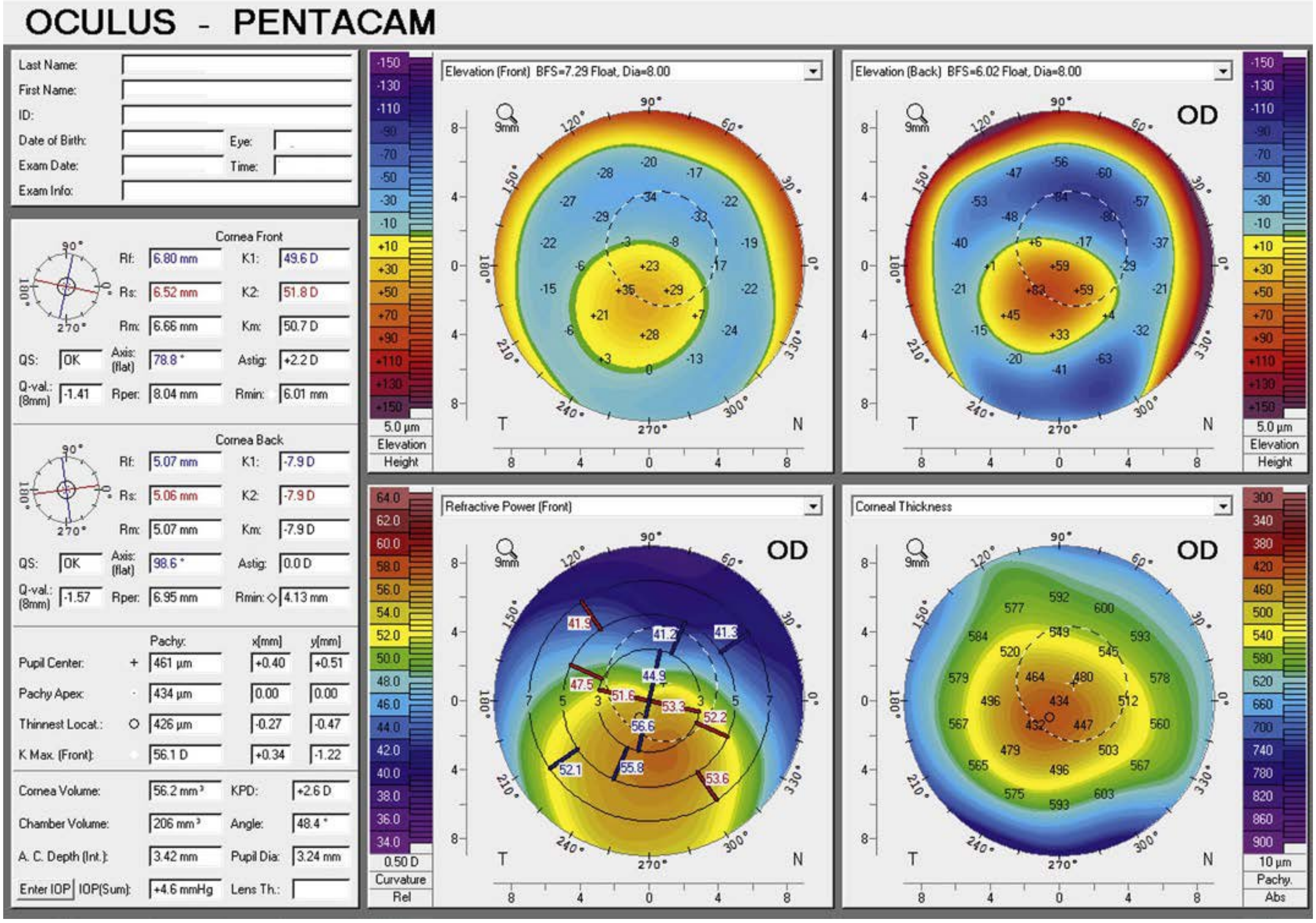
	Axial	Tangential
Normal	 Sim K 44.8 D @52 ° 44.1 D @142 ° ΔK = 0.7 D Pow: Dis: 6.74 mm Ang: 253 ° Universal Standard Scale	 Sim K 44.8 D @52 ° 44.1 D @142 ° ΔK = 0.7 D Pow: Dis: 6.74 mm Ang: 253 ° Universal Standard Scale
Keratoconus with central cone	 Sim K 55.5 D @28 ° 53.1 D @118 ° ΔK = 2.4 D Pow: Dis: 6.74 mm Ang: 253 ° Universal Standard Scale	 Sim K 55.5 D @28 ° 53.1 D @118 ° ΔK = 2.4 D Pow: Dis: 6.74 mm Ang: 253 ° Universal Standard Scale
Keratoconus with inferior cone	 Sim K 51.9 D @58 ° 48.5 D @148 ° ΔK = 3.4 D Pow: Dis: 7.14 mm Ang: 56 ° Universal Standard Scale	 Sim K 51.9 D @58 ° 48.5 D @148 ° ΔK = 3.4 D Pow: Dis: 7.14 mm Ang: 56 ° Universal Standard Scale
Pellucid marginal degeneration	 Sim K 49.5 D @1 ° 39.3 D @91 ° ΔK = 10.2 D Pow: Dis: 7.14 mm Ang: 56 ° Universal Standard Scale	 Sim K 49.5 D @1 ° 39.3 D @91 ° ΔK = 10.2 D Pow: Dis: 7.14 mm Ang: 56 ° Universal Standard Scale

Fig. 37.11 Examples of corneal topography using the Universal Standard Scale (Smolek et al., 2002). The scale highlights abnormally steep curvatures using the colour coding of red or white. Instantaneous (tangential) corneal topography maps in the right column show improved definition of areas of steepening, particularly for conditions further from the central axis such as the pellucid marginal degeneration.



Last Name:
First Name:
ID:
Date of Birth: Eye:
Exam Date: Time:
Exam Info:

Cornea Front

Rf: 6.80 mm K1: 49.6 D
Rs: 6.52 mm K2: 51.8 D
Rm: 6.66 mm Km: 50.7 D
QS: OK Axis: (flat) 78.8 ° Astig: +2.2 D
Q-val.: (8mm) -1.41 Rper: 8.04 mm Rmin: 6.01 mm

Cornea Back

Rf: 5.07 mm K1: -7.9 D
Rs: 5.06 mm K2: -7.9 D
Rm: 5.07 mm Km: -7.9 D
QS: OK Axis: (flat) 98.6 ° Astig: 0.0 D
Q-val.: (8mm) -1.57 Rper: 6.95 mm Rmin: ◇ 4.13 mm

	Pachy:	x[mm]	y[mm]
Pupil Center: +	461 µm	+0.40	+0.51
Pachy Apex:	434 µm	0.00	0.00
Thinnest Locat.: ○	426 µm	-0.27	-0.47
K Max. (Front):	56.1 D	+0.34	-1.22

Cornea Volume: 56.2 mm³ KPD: +2.6 D
Chamber Volume: 206 mm³ Angle: 48.4 °
A. C. Depth (Int.): 3.42 mm Pupil Dia: 3.24 mm
Enter IOP IOP(Sum): +4.6 mmHg Lens Th.:

Fig. 37.12 Corneal tomography quad-map report for a patient with mild–moderate keratoconus (mean-K of 50.7 D). The ectasia is evident in all four maps, but perhaps most in the posterior corneal elevation map (upper right) and corneal pachymetry map (lower right).

Supplementary Tests

There are a number of tests that will not be routinely conducted on all contact lens patients, but may be performed on indication.

CORNEAL SENSITIVITY

If there is reason to suspect that the patient may have anaesthetic corneas, then corneal sensitivity should be assessed. Possible indications could be a history of ocular surgery or corneal infection. Sensitivity may be simply checked clinically, using a wisp of sterile cotton wool touched to the cornea. Approach from the side, so that the patient does not see it coming, and avoid touching the lashes. A normal blink reflex should result from touching the cotton wool to either the corneal apex or limbus. A more sophisticated technique – the Cochet-Bonnet aesthesiometer – can be used to quantify the extent of the deficit of corneal sensitivity.

VISUAL FIELDS

Testing of visual fields should be conducted if the patient has peripheral vision symptoms, if there are questionable fundus signs or if there is an unexplained reduction in acuity. Contact lenses can improve or restrict the visual field, depending upon the type. For example, contact lenses can remove the mid-peripheral scotoma associated with spectacles in hyperopia.

TONOMETRY

Whether the measurement of intraocular pressure is carried out routinely on patients under 40 years of age, or only on indication, will vary between different clinical situations. Although the onset of glaucoma typically occurs in patients over 40 years of age, the clinical examination of a younger patient that reveals extensive optic disc cupping in relation to overall optic disc size, or asymmetry of cupping (difference 0.2), may be an indication for performing tonometry.

STEREOPSIS

Measurement of stereopsis is indicated when binocularity is particularly important to contact lens wear. A good example is contact lens monovision correction for presbyopia, where the monocular near-vision correction can disrupt binocularity. A test of stereopsis can quantify the extent of this disruption (Collins and Bruce, 1994).

COLOUR VISION TESTING

Red–green colour deficiencies occur in an estimated 8% of male and 0.5% of female patients. It may be worthwhile assessing colour vision at least once in all contact lens patients.

Conclusion

The preliminary examination of a prospective contact lens patient is in many respects similar to that which would be conducted on any healthy patient seeking a general eye examination. Perhaps the key distinction is that, in the case of a contact lens patient, consideration is being given to prescribing a device that will come into direct contact with the ocular tissues. In this regard, a thorough examination with the slit-lamp biomicroscope is perhaps the cornerstone of the preliminary examination. More advanced assessments may be indicated if the visual acuity is abnormal, or if there is a history or signs of conditions such as corneal ectasia or surgery. Certainly, the information obtained at this initial visit is of paramount importance because it will provide the baseline findings against which all future observations of the effects of lens wear will be assessed.

Access the complete references list online at http://www.expertconsult.com.

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38

Patient Education

SARAH L MORGAN

Introduction

The quality of instruction and advice given to a patient contributes to the success or failure of the new wearer (Ettinger, 1993). Therefore, the importance of the dispensing visit should not be underestimated, and this chapter covers some of the key aspects of this activity.

OBJECTIVES

Proper and careful tuition of a patient at a dispensing visit will facilitate confident lens handling by the patient and will help to nurture a sound appreciation of how lenses should perform and how to manage various situations that can arise in contact lens wear. Certainly, poor patient education can result in premature discontinuation from lens wear and increase the likelihood of unscheduled visits to the practice.

The dispensing visit seeks to:

- teach the patient the correct methods of lens application and removal
- explain the methods that optimize lens comfort, such as understanding when a lens is inside out or the removal of post-lens debris
- inform the patient about the likely adaptation issues that may be encountered
- outline the correct use of the prescribed care regimen.

TIMING

The availability of diagnostic lens banks has negated the need for individual lens ordering (with the exception of more specialized lenses such as soft toric lenses and the majority of rigid lenses) and has made both the fitting and dispensing appointment possible on the same day. Some patients are so motivated following their first experience of contact lens wear that the dispensing can take place immediately after the initial trial fitting. On the other hand, rescheduling the dispensing visit for another day has the benefits of giving the patient a break after the fitting visit, and allows the patient to read through some preliminary literature about the contact lenses.

Creating the Optimum Teaching Environment

A trained member of support staff rather than the practitioner commonly adopts the teaching role; this person is sometimes referred to as the contact lens hygienist. Having a trained member of the support staff undertaking this task can have several advantages. Some patients feel pressured to have to ‘perform’ in front of the practitioner whereas they may feel more relaxed with a member of the support staff. The delegation of this role requires careful selection of personnel who can be relied upon to provide accurate information to the patient and refer back to the practitioner when necessary (Morgan, 2008).

THE TEACHING AREA

Patients who have elected to wear contact lenses are often apprehensive about the process of lens application and removal. For this reason, the teaching room should be of a comfortable temperature and well ventilated, as many patients become quite anxious in their frustrations if they do not apply the lens on the first attempt. The area should be reasonably private – perhaps screened off from the rest of the practice – and it is essential that the instructor and the patient are free from incidental interruptions. Patients require careful attention when they first handle lenses, and the instructor must not be taken away or distracted from this supervisory task.

Good lighting is important, along with suitable seating for both the patient and the instructor, as flexibility to be able to sit on each side of the patient is needed (Fig. 38.1).

The patient’s chair should be set at a desk such that the patient’s knees can fit comfortably under the desk. This is helpful if the patient accidentally drops the lens during handling.

ACCOUTREMENTS

An illuminated, double-sided (with one side that magnifies), height-adjustable and tilting mirror is ideal. The teaching area must be prepared in advance of the lesson, so that all the following necessary items are to hand:

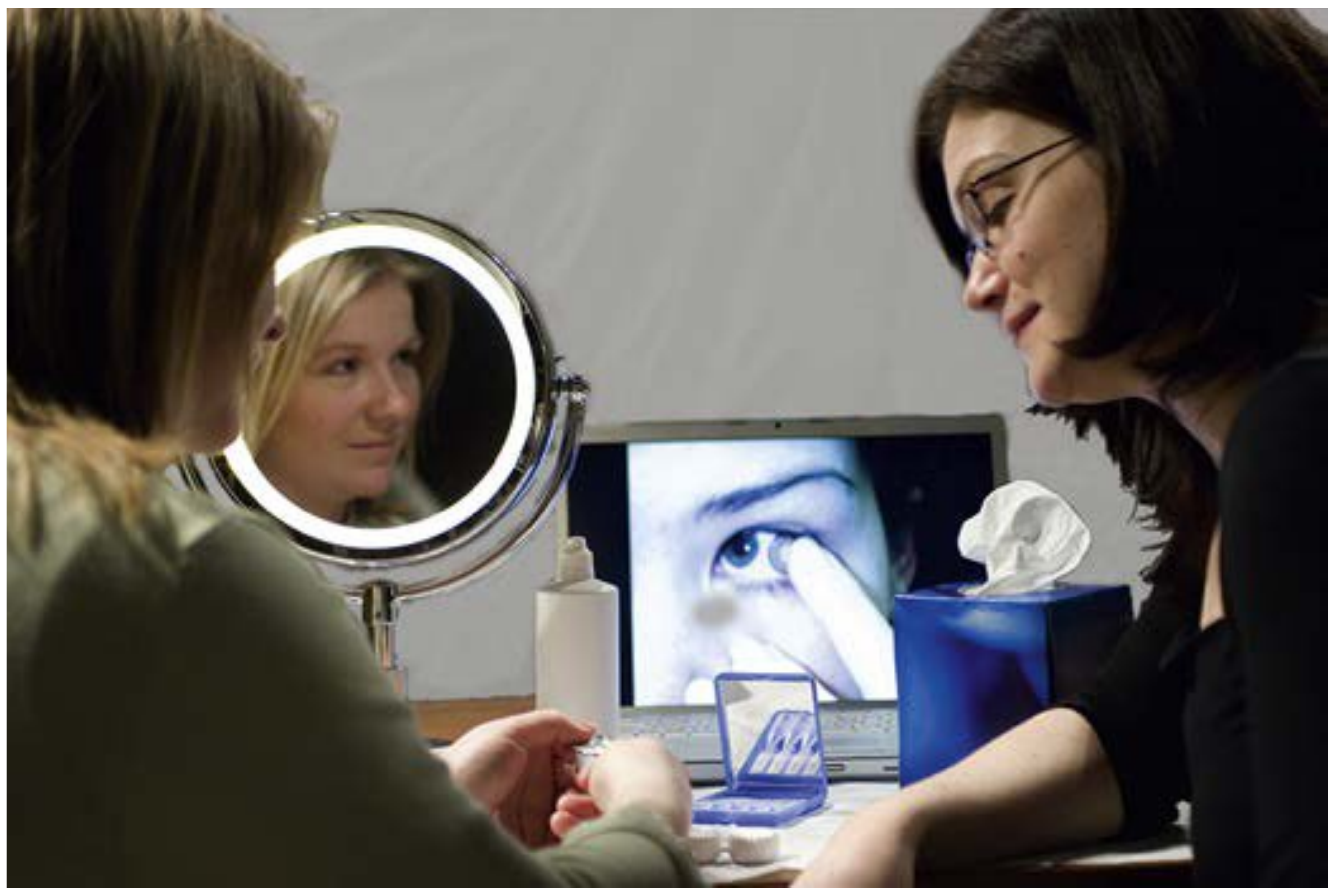

Fig. 38.1 The teaching area should be well illuminated, with seating for both patient and instructor and with all necessary accoutrements immediately to hand.

- contact lenses – cross-checked with the record card and spectacle prescription
- lens case – which may be supplied with the solutions
- trial pack of solutions* – sufficient for the needs of the patient until the first scheduled aftercare visit (*check expiry date)
- additional solution – for rinsing during the lesson
- comfort drops – to help alleviate any ocular discomfort
- box of tissues – with a spare box available
- handwashing facilities – soap (in pump dispenser) and lint-free paper towels
- mirror as described above – cleaned and free from fingerprints
- appropriately sized bag – for the patient to carry away lenses, solutions and accompanying literature.

Patient Instruction

Contact lens handling can be a very frustrating experience for the novice patient. Accordingly, patience and communication skills are the most critical personality traits of the member of staff chosen to instruct contact lens patients. The instruction session should not be rushed, and the patient should feel comfortable asking questions. A good technique is to alternate the practical side of lens application and removal with verbal advice on the wear and care of the lenses (e.g. care, product use, and do's and don'ts). When suitable, coloured or iris-enhancing disposable soft contact lenses should be considered for use during the tuition appointment, and perhaps the first few days of wear, as they provide additional visibility and reassurance of on-eye lens location.

HAND GROOMING AND HYGIENE

The nails of all fingers that are likely to be involved in lens manipulation should be cut short and filed smooth to avoid both lens damage and the potential for corneal insult. It is imperative that the importance of handwashing (and drying) prior to lens handling is reinforced throughout the instruction phase. The best way of achieving this without appearing to be patronizing to the patient is for the instructor to wash his/her hands prior to lens handling, in full view of the patient. A very brief explanation as to why this is so important – the prevention of lens contamination and reducing the risks of infection – can be given to the patient. The patient can then be invited to wash his/her hands. At all future instruction or aftercare visits, patients should be prompted to wash their hands if they forget to do this before proceeding to handle lenses.

LID MANIPULATION

Touching the eye area can be awkward for many patients. The patient must first practise how to overcome the natural blink reflex, and this can be achieved by way of a 'dry run,' in that the patient is not handling the lens at first. It is usual for the instructor to perform each part of the handling process before the patient tries. Effective upper-lid control is crucial to lens application.

Most patients will prefer to apply lenses onto each eye using the same hand, whereas some will use the right hand to apply the right lens and the left hand to apply the left lens. Consider, by way of example, a 'dry run' for lens application onto the right eye with the right hand. The patient is given the following instructions:

In order to take control of your right upper lid, look downwards so that the whole of the upper lid is exposed. Next, bringing your left hand vertically over your forehead, place the fingertip of your middle finger on your lid margin close to the eyelashes and gently draw the lid upwards and hold it against your brow bone (Fig. 38.2).

Now look straight into the mirror, and place the middle finger of your right hand on the middle of your lower lid and gently retract the lower lid (Fig. 38.3). (This further increases the palpebral aperture and helps to stabilize the hand applying the lens.) The forefinger of your right hand is then free to apply the lens directly onto your eye.

Once the patient has mastered lid manipulation, lens handling can be taught.

LENS INSPECTION

Practitioners routinely inspect lenses prior to application for evidence of lens damage, debris and whether a soft lens is inside out or not. Patients need this basic level of instruction, even to the level of detail of explaining how to remove the lens from the lens packaging and also how to replace and remove a lens carefully from the lens case to avoid lens damage; this is particularly relevant to basket-style cases for soft lenses, which clip shut, and

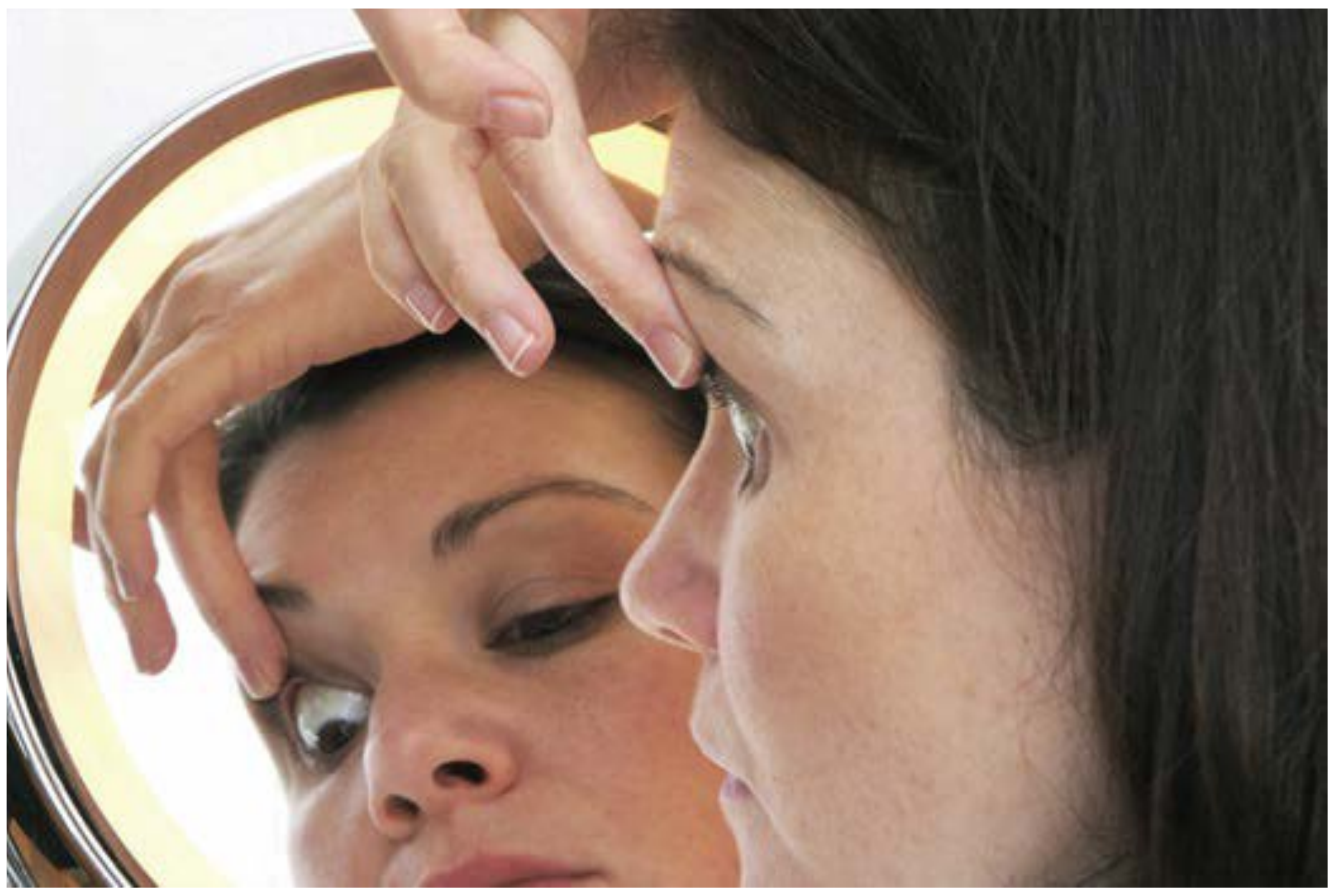

Fig. 38.2 Taking control of the upper lid.

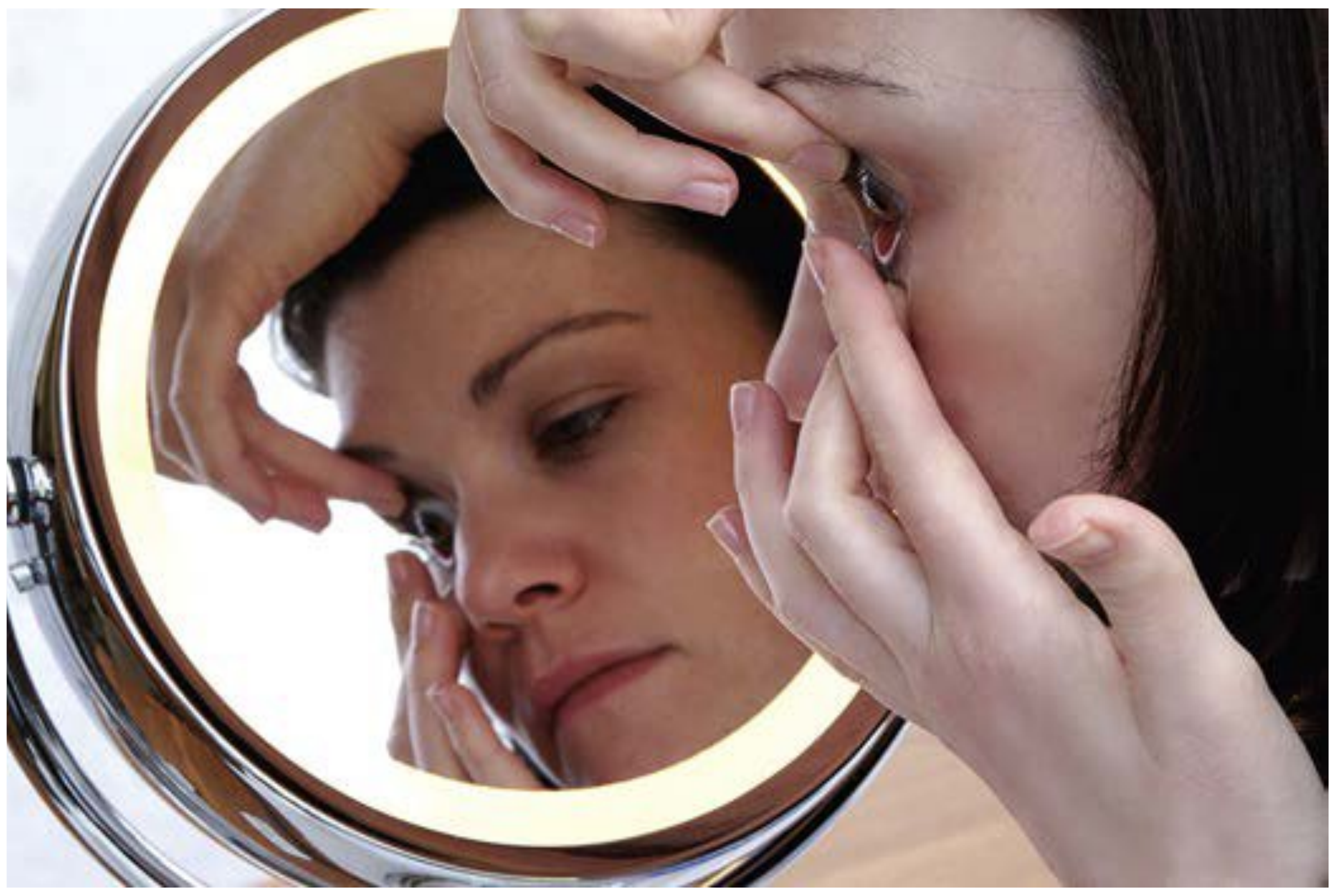

Fig. 38.3 With both lids retracted the patient is ready to apply the lens.

barrel cases with lens supports for rigid lenses. Patients need reassurance that a soft contact lens applied inside-out is not harmful, but such a lens may be slightly uncomfortable and may be prone to move excessively, which in turn can affect vision performance and in some cases cause the lens to be blinked out.

For the experienced contact lens practitioner, careful passive inspection of the lens on the tip of the finger will reveal whether the lens is inside out or not. However, for the novice, assessing soft lens inversion can be difficult. An active approach can be more enlightening; the lens is allowed to dehydrate for a few seconds, and then, with the lens placed in the crease of the palm of the hand, the lens edges are moved together by cupping the hand as if intending to fold it in half – this is called the 'taco test', as a lens that is the right way around curls up rather like a taco shell. If the lens edges appear to curl towards each other, the lens is the right way around (Fig. 38.4A), and if the edges appear to curl outwards, the lens is probably inside out (Fig. 38.4B). Typically, a practitioner would utilize this technique by placing the lens on the tip of the finger; however, by definition, a new wearer finds lens manipulation a challenge so the hand technique is both easier to teach and more practical for the patient.

It may be necessary to invert the lens repeatedly in order to confirm this; the drier the lens becomes, the more apparent the inversion status of the lens will be. For the novice wearer, the instructor may deliberately ask the patient to first apply one lens the correct way around, and then the other lens inside out, asking the patient to comment on the difference. This serves as a good demonstration of the difference in sensation from an inside-out lens to a lens placed the correct way round – the direct comparison may be needed for the patient to appreciate the difference. New wearers may consider themselves to be 'unsuitable' for contact lenses if they intermittently apply one or both lenses inside out during their first few days of lens wear. Attention to teaching lens inversion, as well as proactively demonstrating the sensation of an inverted lens, may help to reduce drop-out rates at this early stage.

Some manufacturers mark their lenses with an inversion indicator. When viewed from a designated aspect, letters or a number sequence can be observed in the correct orientation. If the lens is inverted, the letters or number sequence will be reversed (incorrect) when viewed from the same aspect. Patients should be advised of any other markings on the lenses, and their purpose if known (such as toric lens scribe marks) so that they are aware that these features are meant to be present on the lens and are not a hair or defect.

When handling lenses, the forefinger applying the lens needs to be as dry as possible. On removing the lens from the case or packaging, it should be placed in the palm of the opposite hand to help drain off excess solution. The lens can then be 'scooped up' from the palm by the side of the fingertip of the forefinger with some aid from the forefinger and thumb of the opposite hand. Tissues on the desk – preferably lint free – can be used to dab the forefinger dry during this process. In the case of soft lenses, the lens may need to be lifted off the forefinger to dry the fingertip so as to prevent the lens from sagging back over a wet fingertip owing to surface tension. The complete circumference of the lens should be sitting proud of the finger.

LENS APPLICATION

Soft lens application requires a slow-motion approach. The patient must not release the upper lid too soon, as this can lead to the lens being ejected owing to air trapped behind the lens. The instructor should sit beside the patient rather than across the desk because, first, this is less confrontational, and second, a better view of the actions of the patient is possible. When the right lens is applied and removed, the instructor should sit on the right side of the patient and vice versa. The patient should be directed to apply the lower edge of a soft contact lens to the area 1–2 mm below the limbus at an angle of 45°, having vaulted the lower lid (Fig. 38.5).

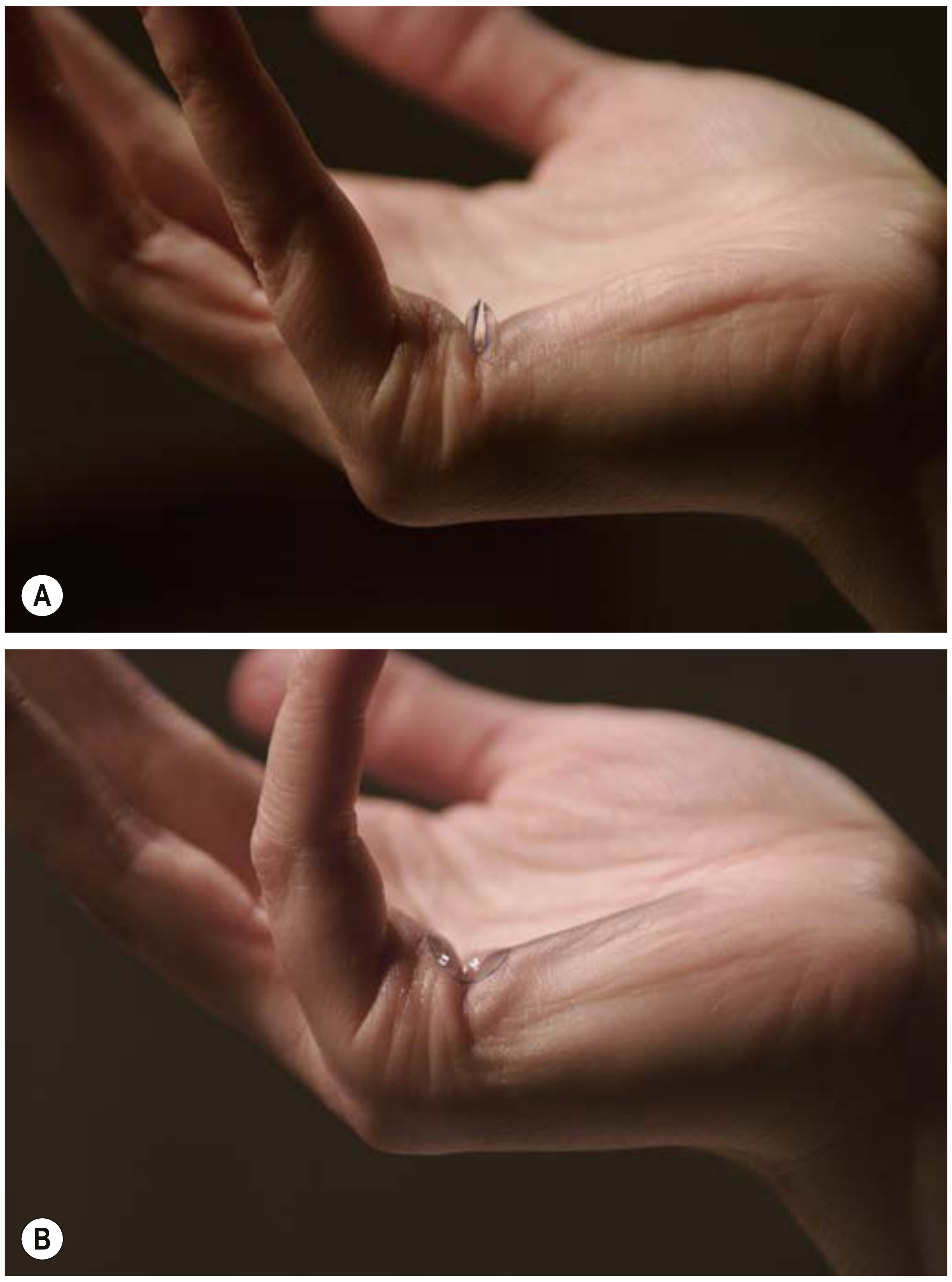

Fig. 38.4 A simple technique for checking whether a soft lens is inverted. (A) Right way; (B) wrong way.

Once contact with the tear film has been made, the contact lens is attracted to the cornea. If there are any air bubbles underneath the lens, these can be overcome by the patient looking downwards and slowly releasing the upper lid whilst still looking down and then closing the eye tight so as to squeeze out the remaining air.

A rigid lens, being of smaller diameter, is easier to apply, and its shape remains consistent throughout handling. Rigid lenses should be placed directly onto the central cornea as failure to do so can lead to the lens being displaced onto the conjunctiva.

Some patients have flexibility problems with their arms and / or hands, so common-sense adaptations to the usual recommended approach will need to be made. For example, one-handed application can be achieved with the patient dipping the chin towards the chest and looking upwards into the mirror. This serves to provide a larger area inferior to the limbus on which to apply a soft lens, and the lens, once applied, can be

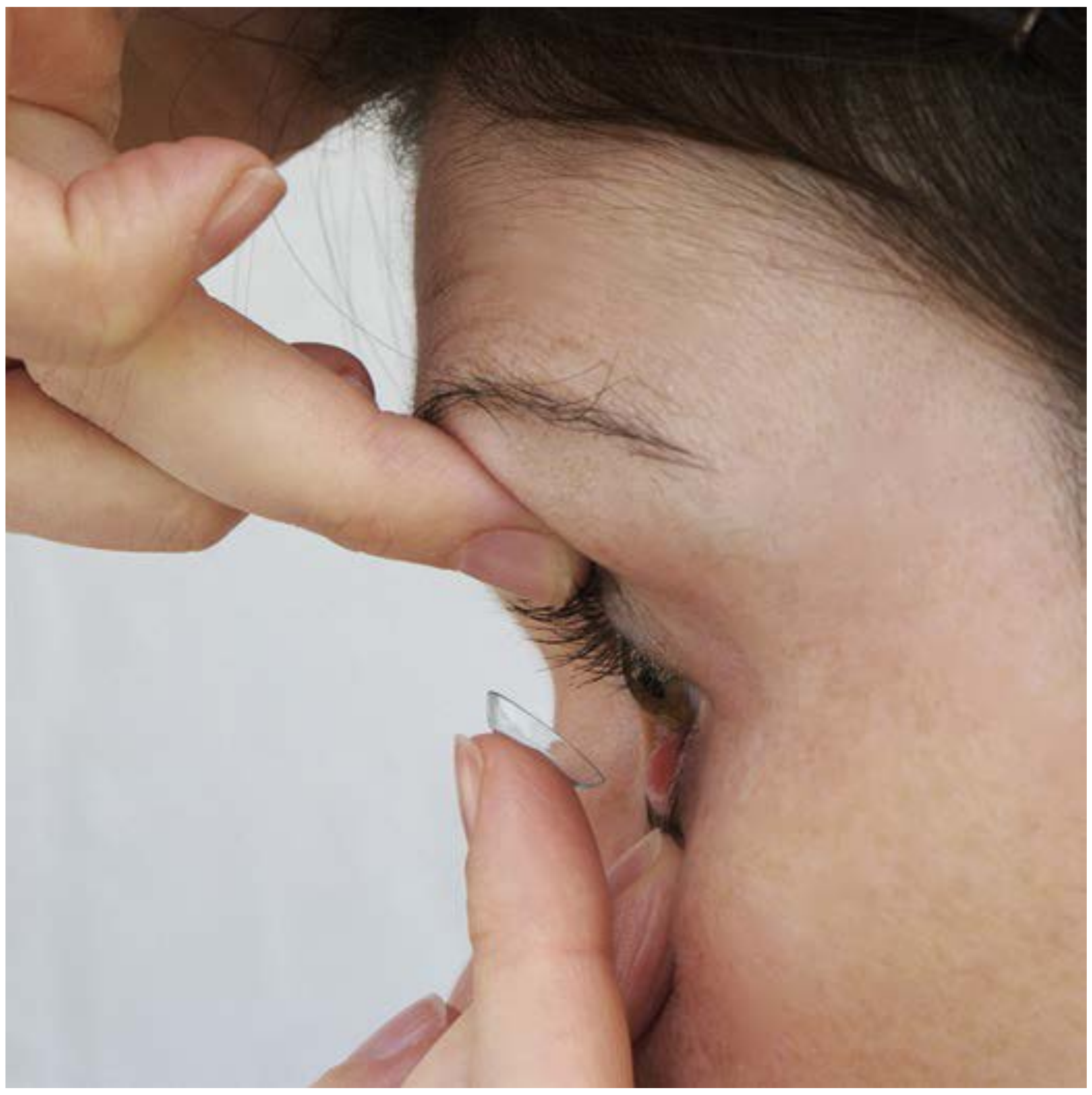

Fig. 38.5 The lens is best applied at an angle of 45° to the cornea.

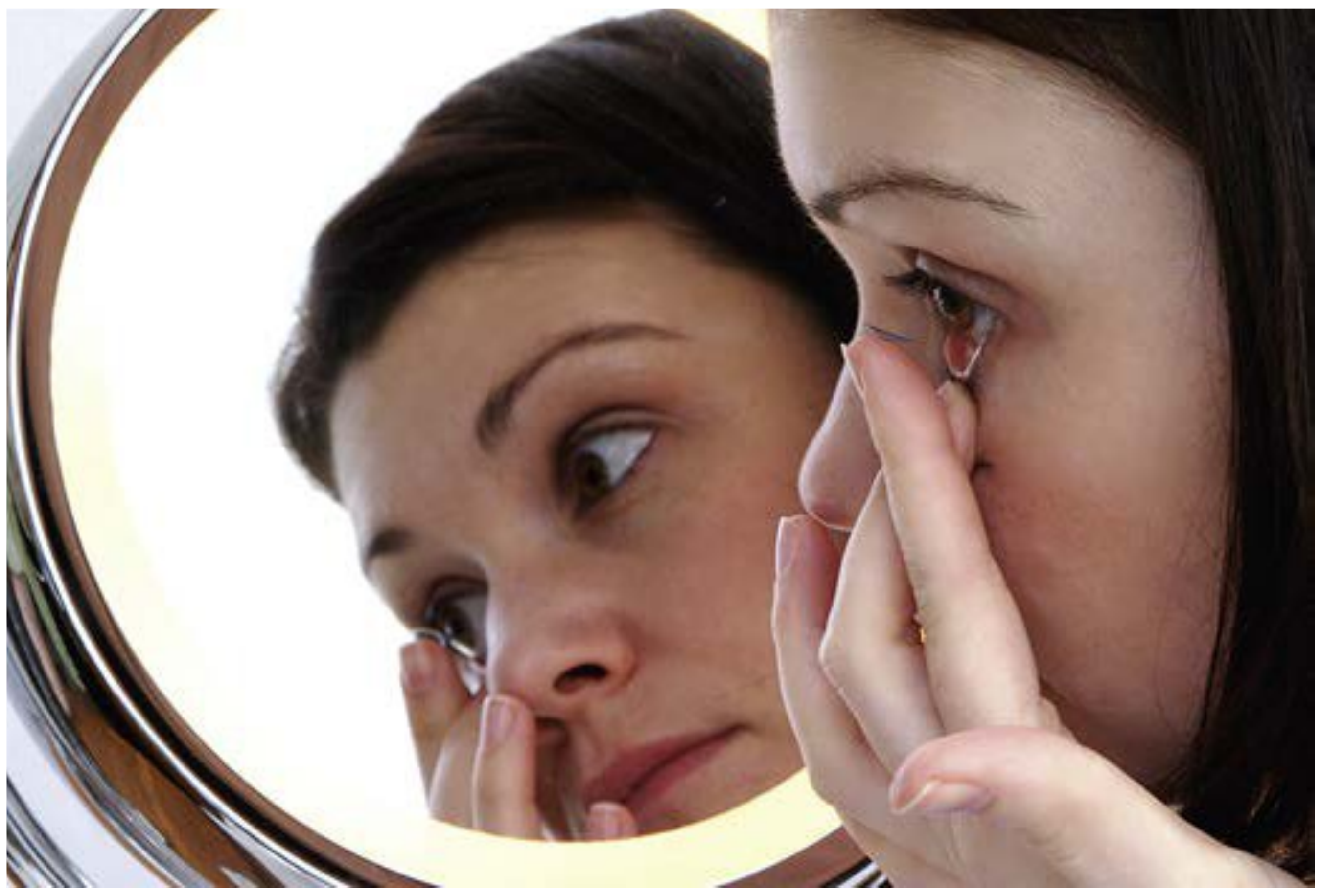

Fig. 38.6 One-handed lens application.

manipulated into place. A rigid lens can be applied directly onto the cornea using this method (Fig. 38.6).

Having applied the lens, the patient can check that it is in position by covering the other eye and checking that vision is as clear as expected. For patients wearing monovision correction, the near lens should be applied first so that application of the distance lens is easier. In other cases, developing a habit of handling the right lens first for both application and removal helps to avoid mixing up the two lenses.

TIPS ON COMFORT AND LENS RECENTRING

Contact lenses can attract debris during lens preparation prior to application and wearers can experience some mild lens awareness. In the case of soft lenses, sliding the lens temporally onto the conjunctiva can relieve this (Fig. 38.7).

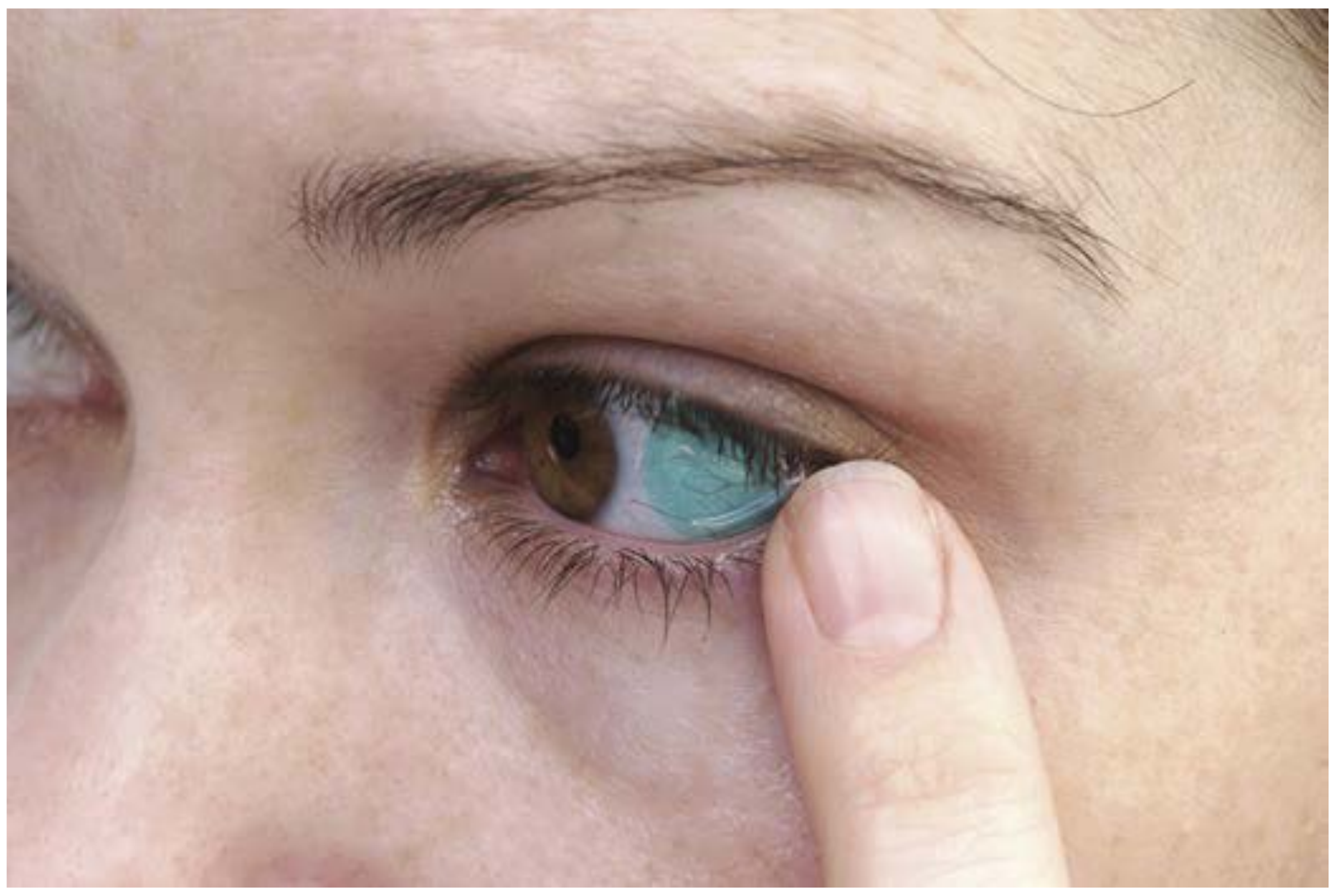

Fig. 38.7 Displacing a soft contact lens laterally is a useful technique for removing debris from behind the lens.

For the right eye, the patient looks directly into the mirror and turns the head to the right whilst maintaining a straight-ahead gaze. This helps to expose a large area of temporal conjunctiva onto which the lens can be displaced. Using the right hand, the patient displaces the inferior lid slightly with the middle finger and slides the lens completely off the cornea and onto the temporal conjunctiva using the forefinger. The patient will usually experience instant relief from any previous foreign-body sensation. At this point, the patient blinks three to five times, which washes the tear film over the cornea, thereby displacing any unwanted debris. The lens can be manually repositioned onto the cornea, or alternatively the patient can look temporally with a couple of blinks, which will achieve the same result. If this type of discomfort is experienced on application of a rigid lens, the lens should be removed, rinsed and reapplied. With soft lenses, if a foreign-body sensation persists after this technique has been tried, the lens should be removed, rinsed and inspected for any signs of damage; the lens can then be reapplied if all looks well (or replaced if damaged).

If a rigid lens is decentred from the cornea onto the conjunctiva, the patient must attempt to manoeuvre the lens onto the cornea by holding the upper and lower edges of the lens through the lids and gently lifting the lens edges to allow tears to flow underneath the lens, which in turn helps to release the lens and allows manipulation back onto the cornea. Locating the lens in the first instance may require careful observation using the mirror as well as lifting the upper lid to investigate whether the lens has been displaced vertically. This is a good moment to inform the new wearer that contact lenses can never 'disappear behind the eyes' and 'float into the brain', which is a commonly held misconception requiring reassurance, anatomical information and education. The instructor should explain that a lens can move only under the upper lid (the most common place for a lens to 'disappear') or perhaps behind the lower lid. Most rigid lenses can be felt through the lid because of their rigidity, whereas soft lenses can be more difficult to locate, especially if they have folded in half before being swept up under the upper lid. The instillation of comfort drops may suffice, or saline solution (via an eye bath) can be helpful in releasing lenses in this situation. Comparing the front aspect of the eye to a 'pocket' is a good analogy to use, which serves to convince the patient of the very limited range of displacement of the lens.

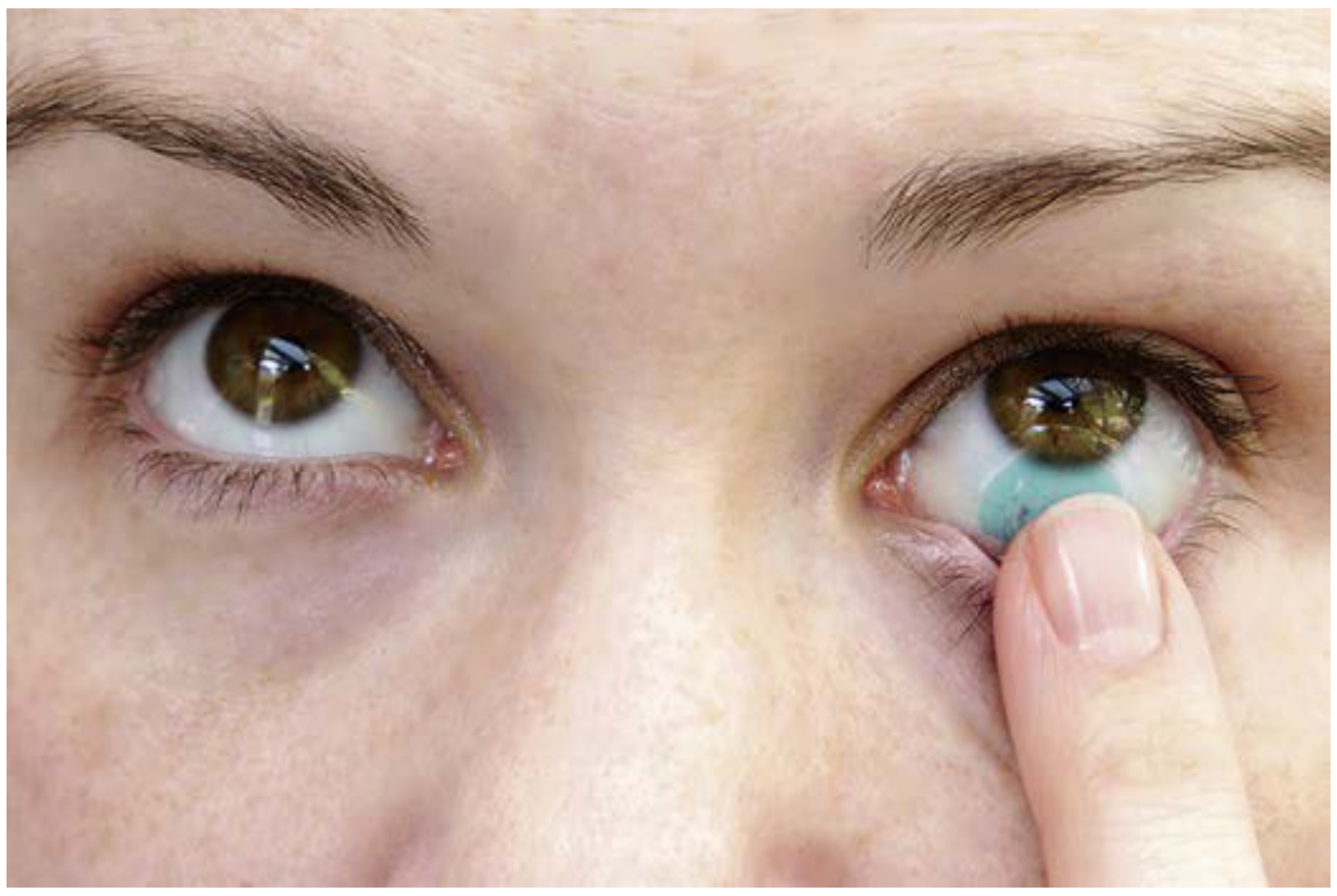

Fig. 38.8 A soft lens should be displaced downwards prior to removal.

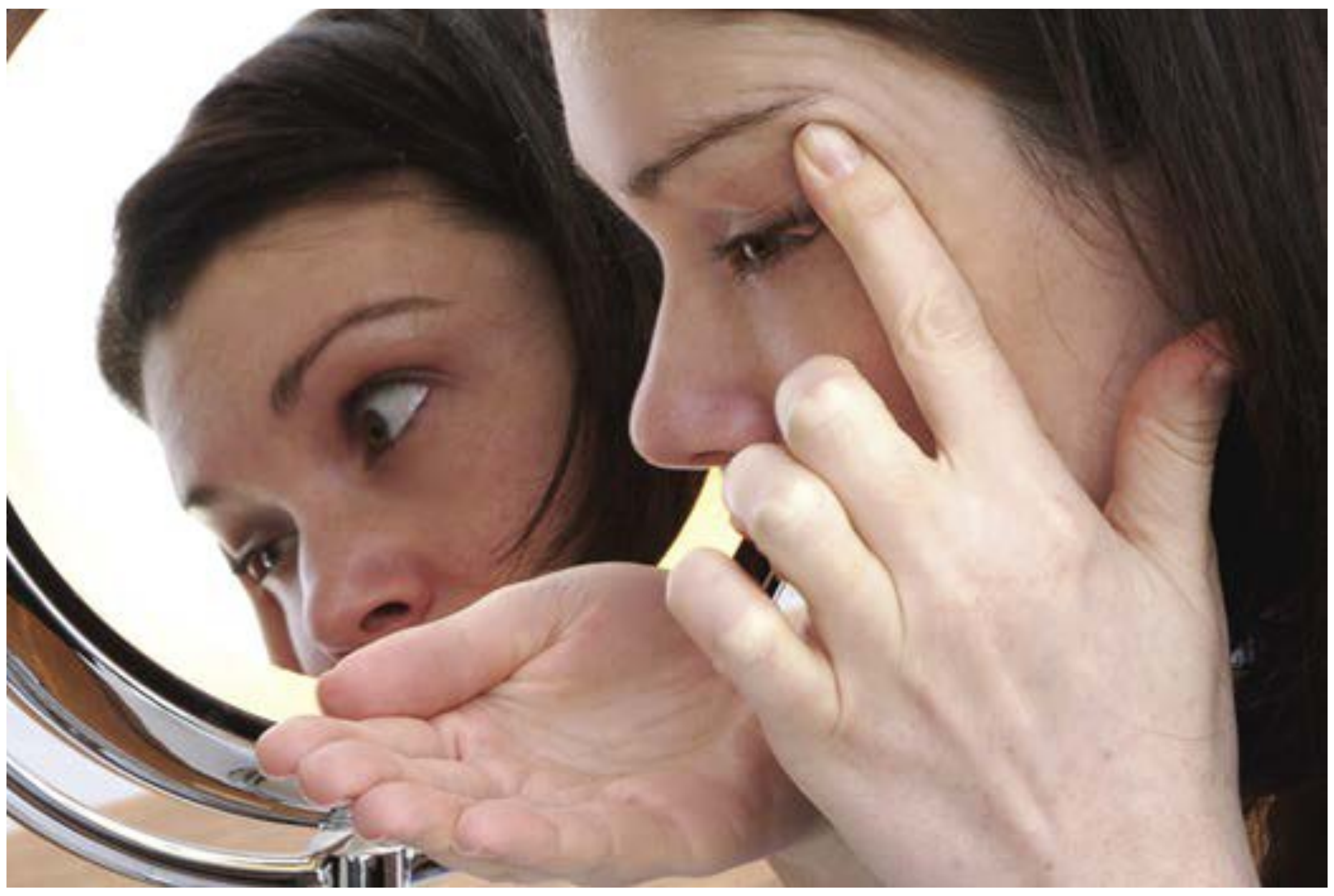

Fig. 38.10 The blink technique for rigid lens removal.

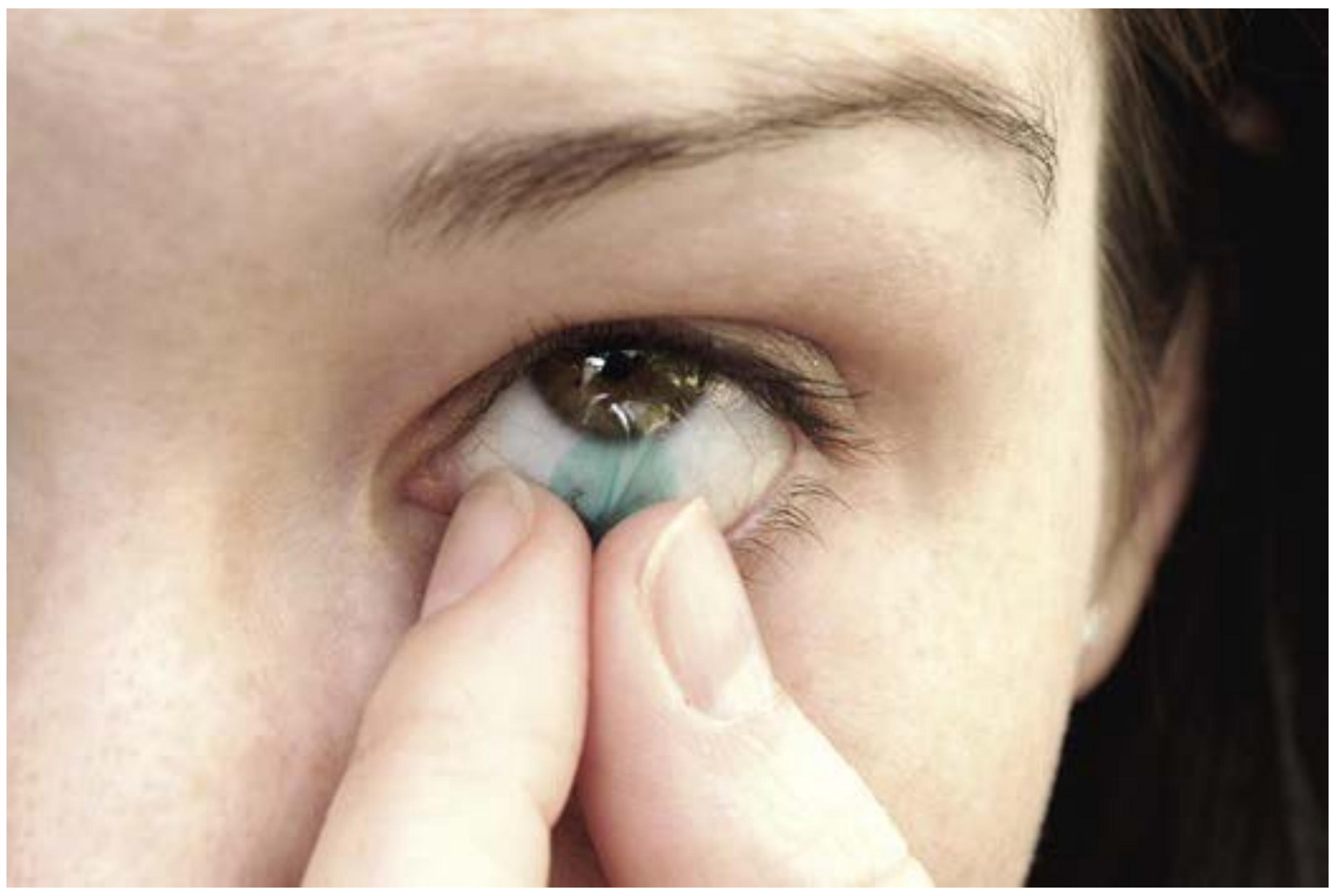

Fig. 38.9 Soft lens removal.

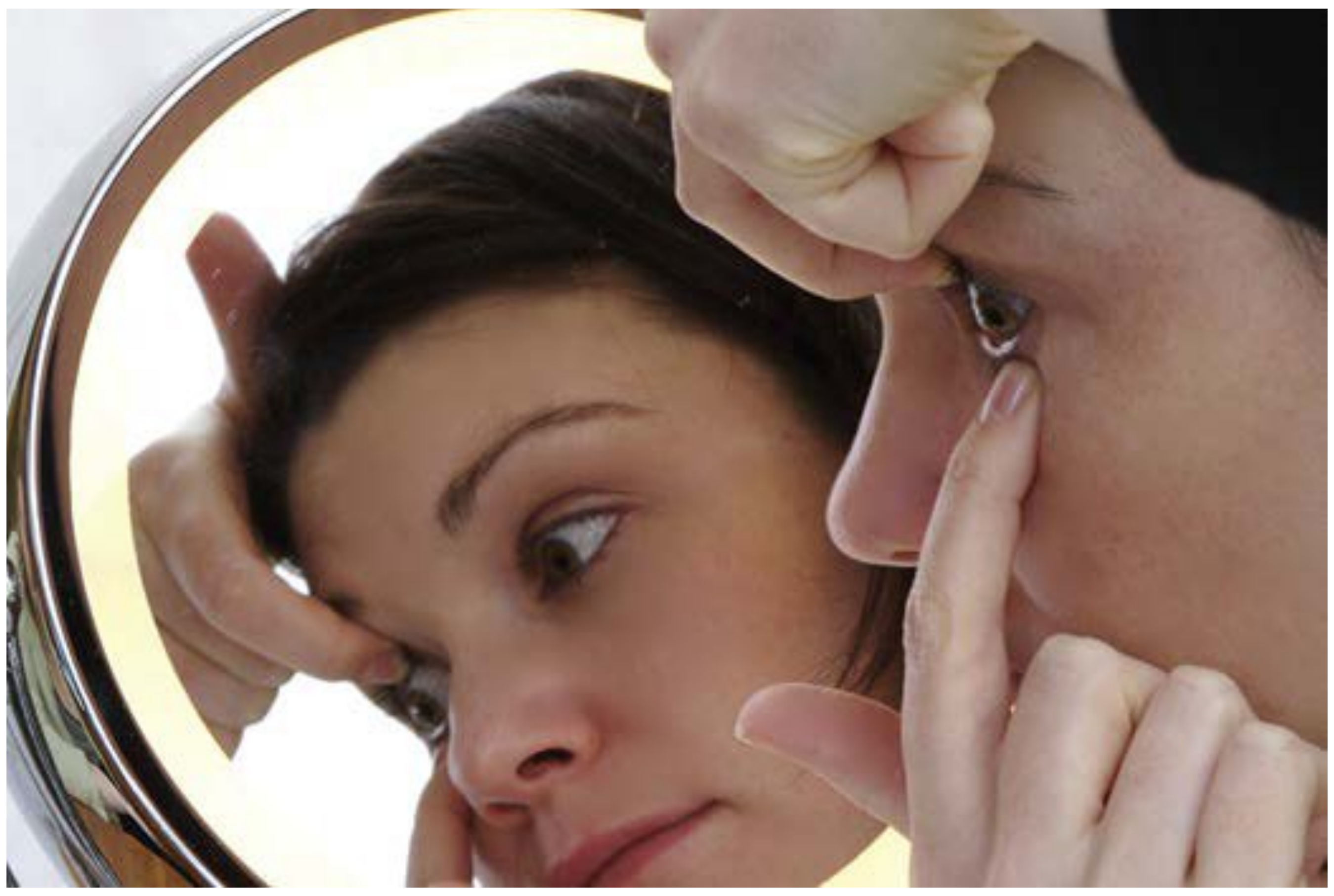

Fig. 38.11 The two-handed technique for rigid lens removal.

LENS REMOVAL

Whilst soft lenses are more difficult to apply than rigid lenses, they can be easier to remove. Soft lens removal must be achievable in any situation, so it is recommended that patients learn how to remove lenses without the aid of a mirror. The chance of causing a corneal abrasion on lens removal must be given consideration; thus, removal of soft lenses from the more resilient conjunctiva is preferable. The back surface of a soft lens is designed to align closely with the cornea, so displacing the lens onto the conjunctiva helps to loosen the attachment of the lens, thereby aiding removal.

To remove a soft lens from the right eye, the patient rests the middle finger of the preferred hand on the lower-lid margin, displacing it away from the globe slightly, looks upwards and then slides the lens downwards onto the inferior conjunctiva using the forefinger (Fig. 38.8).

Whilst still touching the lens with the forefinger, the thumb of the same hand can be brought in to pinch the lens off the conjunctiva, thereby completing lens removal (Fig. 38.9).

Sometimes a few attempts are necessary with instructor guidance until the patient becomes aware of the sensation of lens displacement and of gripping the lens between the thumb and forefinger.

The technique for rigid lens removal is patient dependent. Some patients can more easily spring the lens out using their lids; others, however, need to employ a different method.

The Blink Technique

This technique utilizes the natural narrowing of the palpebral aperture and lid margin tension to get behind the lens to 'flip' it out (Fig. 38.10).

With this technique, the patient first stares very wide to ensure the lid margins are beyond and not over the lens edge. The eye of the patient needs to be as central as possible in the palpebral aperture to achieve this. The patient then places the forefinger only on the outer canthus whilst pulling temporally to make the lids taut. Once the patient feels the edge of the lens, a forceful blink may flip the lens out. Sometimes it is necessary for the patient to look slightly nasally in order to position the cornea and lens in an area of narrower aperture.

The Two-handed Technique

This method involves manually tensioning the lids against the lens edge (Fig. 38.11).

For the right eye, the patient positions the forefinger of the left hand on the middle edge of the upper lid and the forefinger of the right hand on the middle edge of the lower lid. The lids are first moved apart to ensure that the lens is free to move, and they are then moved into the globe to tighten against the lens edge. Slightly more pressure is applied to the upper lid in order to flip the lens out over the lower lid with the top of the lens being released first. Care must be taken that the lens edge is not forced into the cornea itself.

Suction Holders

Special rigid lens suction holders are available, although these have three key disadvantages:

1. If patients are able to remove the lens only with the aid of this device, they will be unable to remove the lens in an emergency without it
2. An inexperienced wearer may fail to attach the suction holder to the lens and bring the holder in contact with either the cornea or conjunctiva
3. Proper hygiene of the suction cup is required: it may be an additional source of contamination of the contact lenses (Boost and Cho, 2005).

In these respects, the use of suction holders is not advocated.

Patients must be able to remove their contact lenses safely before taking them away. For new wearers, performing this routine three times is recommended. For existing wearers new to the practice or having been fitted with a new lens with subtly different handling characteristics, demonstrating the established technique once usually suffices. Some practitioners, when refitting patients who are new to the practice, assume that they follow a good routine with respect to lens wear and care. It may be prudent in an age of litigation that all patients undergo some degree of in-practice training as well as signing an informed consent form so that there is a written record that the patient understands the correct protocols for lens wear and care. Periodically, all established lens wearers may be updated in this way to ensure they are aware of current advice and the recommended practice protocols.

CARE PRODUCTS

The full care regimen should be demonstrated from start to finish, explaining why each step is necessary as well as what could happen if the routine is not strictly adhered to. The patient should be handed written information about the care products being dispensed; this may be information that is supplied by the manufacturer and/or material prepared by the practitioner.

Having applied and removed lenses a couple of times, the patient may appreciate a comfort drop in each eye. This serves to demonstrate the benefit of ocular lubricants as well as teaching the patient how to instill comfort drops when wearing lenses. Instances in which comfort drops provide symptomatic relief – such as during prolonged near work when blink rates are reduced, and in dry atmospheres (e.g. during flights) – can be discussed. The dangers of using tap water and saliva as rewetting agents can be outlined (Shovlin, 1990), as well as the appropriateness or otherwise of using prescribed and over-the-counter eye drops when wearing lenses. Patients should be aware that persistent lens discomfort should not be ignored, and that lens removal is indicated in this instance.

COSMETICS

For contact lens wearers using cosmetics, advice from the practitioner about their safe use should be given. Contact lenses can readily become soiled or damaged as a result of contamination from various cosmetic products (Tlachac, 1994). Also, some make-up removers and waterproof mascaras can change the shape and optical performance of some silicone hydrogel lenses (Luensmann et al., 2015) and some mascaras can deposit on the surface of silicone hydrogel lenses and reduce lens surface wettability (Srinivasan et al., 2015), which could have an impact on various aspects of in vivo lens performance.

Some tips for cosmetic use by lens wearers (Association of Contact Lens Manufacturers, 2009):

- Always wash your hands before handling your lenses; avoid perfumed or medicated soaps.
- Apply your contact lenses before applying make-up. This will help you to see what you are doing while applying your cosmetics.
- Close your eyes when applying loose powder, to keep it from getting in your eyes.
- Stay away from make-up and cleansers that can leave a greasy film on lenses. The same goes for hand creams and lotions; put these on after handling your lenses.
- Avoid using 'lash extender' mascaras, as they contain fibres that can flake off and get into your eyes, causing possible irritation.
- Cream or liquid blushers, eyeshadows and eyeliners are preferable since they do not contain gritty substances that can irritate your eyes. If you use powdered eyeshadow, make sure to apply it with a wet applicator. Do not use frosted shadows, as they contain tinsel, an ingredient that will stain your lenses.
- Never apply your eyeliner on the inside part of your lid. It could get on your contact lenses, blurring vision and irritating your eyes.
- Look out for cosmetics designed especially for contact lens wearers.
- It is best not to use hairsprays and other aerosol products after applying your lenses. If you find it necessary to apply hairspray when you are wearing lenses, close your eyes.
- Store your make-up properly, making sure lids are tightly sealed. Replace mascara and applicators at least every 3 months to avoid bacteria build-up.

WEARING SCHEDULES

In the past, all patients were advised to adopt a wearing schedule, which means progressively increasing lens wearing time when wearing lenses for the first time, or after not having worn lenses for a prolonged period. The said purpose of advising adherence to a wearing schedule was to allow patients to adapt to lenses. Failure to adapt to early-generation, low-oxygen-performance polymethyl methacrylate (PMMA) and thick soft lenses – by exceeding the adaptation wearing schedule – resulted in worsening discomfort and red and watery eyes towards the end of the wearing period. The physiological basis of this adaptation process remains unclear, but it appears to be related to the effects of lens-induced hypoxia.

Soft Lenses

The introduction of 1-day disposable soft lenses in the mid 1990s has meant that a number of patients wear their lenses on a part-time basis. Soft contact lens wearers used to be advised to wear their lenses for no more than 4 hours on the first day and increase the next consecutive wearing days by no more than 2 hours each day up to a maximum of 12 hours wear per day. New modalities and improvements in soft lens materials and designs have now largely rendered this approach redundant.

Some gradual adaptation may be advised if the patient is working towards full-time wear or when a patient is particularly sensitive to lens wear. Inevitably, the more frequently lenses are worn, the greater is the level of adaptation. Patients should be warned not to overwear daily-wear non-silicone hydrogel soft contact lenses in spite of how comfortable they may feel.

For new lens wearers embarking on continuous wear of lenses, a week of daily wear is advised prior to sleeping in them (Maldonado-Codina et al., 2005). This serves two purposes: (1) ensuring the patient is adapted to lens wear; and (2) ensuring the patient is proficient in lens handling.

Rigid Lenses

Rigid lenses require a longer adaptation period. Topical anaesthetics have been advocated by some practitioners to alleviate discomfort during the fitting appointment and the dispensing visit (Bennett et al., 1998). Nominally, patients are instructed to wear lenses on the first day for about 2 hours, and building up by an extra 2 hours per day. Some practitioners accelerate this process by advising patients to wear lenses in the morning, followed by a break during the afternoon, and then to recommence wear in the evening. The adaptation process is patient dependent, and the patient's own level of comfort can act as a guide.

It sometimes takes a few days for the surface of rigid lenses to attain an optimal level of wettability and comfort for a variety of reasons. First, some hydrophobic polishing compounds may not have been completely removed from the lens surface prior to delivery (thorough lens cleaning prior to dispensing the lens to the patient can alleviate such problems). Second, until becoming coated with natural constituents of the tears, rigid lenses may remain slightly hydrophobic on the first day of wear, especially if they have been delivered in a dry state (storing rigid lenses in solution for about 24 hours prior to dispensing will minimize this effect) (Bourassa and Benjamin, 1992).

RECOGNIZING AN EMERGENCY

Patients need to know how to identify an emergency situation when wearing lenses, in the same way that flight attendants go through the routine emergency procedure at the start of all flights. In addition to this, new wearers need to be aware of normal adaptation symptoms such as mild foreign-body sensation and intermittent blurring of vision. If a contact lens wearer is concerned that there is a problem, he/she can be advised to check that the eyes 'look good, feel good and see good (well)'. This easy-to-remember adage refers to the following:

- 'look good' – there is no more ocular redness than normal
- 'feel good' – their eyes feel comfortable prior to and after lens application
- 'see good (well)' – their vision is what they would usually expect (each eye checked monocularly).

Any significant redness when accompanied by pain needs urgent practitioner attention, which may also require medical treatment, especially if the redness and pain do not ease following lens removal. Visual losses should not automatically be put down to contact lens wear, as there may be some form of ocular pathology present that is unrelated to lens wear. The current spectacles can be used by the patient as another method of checking the vision in each eye monocularly.

PATIENT DISCHARGE

A useful strategy to instil confidence in patients who have never worn lenses previously is to have the patient apply the lenses at the conclusion of the training session, and to leave the practice wearing the lenses. The patient will then be forced to confront the challenge of lens handling (at least lens removal in the first instance), rather than, as might occur, putting the lenses aside until enough courage can be mustered to wear lenses at a later date.

An aftercare appointment should be made before the patient leaves the practice with the new contact lenses. Practice staff must be vigilant about the attendance of new wearers to their first follow-up appointment. Any no-shows or cancellations should be contacted by a member of staff (ideally the person who conducted the instruction appointment) to enquire about the progress with lens wear. A new wearer may be too embarrassed to return with minor handling difficulties or perhaps the simple loss of, or damage to, one of their trial lenses. Significant time is spent fitting and teaching the patient, so a new wearer does not fail at this final hurdle when a few more minutes of instruction (or perhaps one replacement lens) would lead to a lifetime of successful lens wear. The patient must appreciate that ongoing success with contact lenses is dependent upon several factors, such as adaptation to the lenses, compliance with the instructions given and attendance for regular aftercare visits. It should be impressed upon the patient that, although good vision and comfort are indicators of success, this does not automatically prove optimum product choice and individual compatibility. All wearers must be made aware of the importance of regular biomicroscopic examination. The standard strategy for encouraging compliance with the requirement to return for regular aftercare visits is to restrict the supply of lenses issued to the patient to correspond with the desired time period between aftercare appointments. Patients should also be made aware of the regularity of contact lens types and ancillary products becoming available, so attendance for aftercare visits ensures that they are advised about the most up-to-date product choices for their individual needs.

Informed Consent

Informed consent means that a patient embarking on contact lens wear should be made aware of both the risks and benefits of contact lens wear as well as having the opportunity to ask questions (Rosenwasser, 1991; Roberts et al., 2005). The information provided verbally should be reinforced with written material. As well as providing the patient with information about the recommended lenses and/or solution system of choice, the practitioner must also have discussed the possible alternatives.

A comprehensive list of every possible contact lens complication does not need to be discussed, but a practitioner is required to discuss those that a reasonable person or members of the profession would expect to be told. A practitioner would be expected to mention the more common non-serious aspects of lens wear, such as the normal adaptation symptoms, in addition to the less common risks that could lead to a serious complication such as visual loss from corneal infection.

Prospective wearers should also be made aware of the consequences of not following the recommended instructions. This may be perceived by some practitioners as a negative approach, as it does not present contact lenses in a positive light. However, discussing such possible scenarios will preclude patients from claiming lack of informed consent if they are non-compliant with advice. There is no legal stipulation regarding the provision of information when prescribing a contact lens; however, providing information and obtaining informed consent form part of good clinical practice. Although written consent is not evidence that informed discussion has taken place, written agreements can be used to provide a basis for the process.

A standard form can be used, which the patient signs to acknowledge that he/she has been given the necessary advice and instructions (Rosenwasser, 1991). The patient should be given a copy of this with the other copy retained in the records. In the case of minors, the form should be signed by both the child (where possible) and the parent or guardian.

Conclusion

The success of the dispensing visit is fundamental to the future welfare of the contact lens patient. Careful preparation and skilful instruction are involved in setting the patient on the road to success. Although this function is commonly and appropriately delegated to support staff, the practitioner must feel confident in the training and instruction routine so that all aspects of contact lens wear and care are covered. Written information in addition to booklets provided by manufacturers are essential accompaniments for this visit as well as a requirement of signing the statement of informed consent.

Access the complete references list online at http://www.expertconsult.com.

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Aftercare

LORETTA B SZCZOTKA-FLYNN | NATHAN EFRON

Introduction

Contact lenses are generally very well tolerated by the majority of patients; however, appropriate aftercare of the contact lens patient is essential to ensure that long-term success is maintained. Aftercare procedures are equally as important as the original lens fitting because the lenses that were fitted initially may develop unanticipated complications, which require correction at any time during postfitting patient care. In fact, it is commonly held that contact lens aftercare represents a continuum and as such can never be considered to be complete.

Postfitting care can be considered as ‘early’ or ‘late’ aftercare. Early aftercare usually encompasses the first 3 months after lens dispensing and is generally considered part of the initial lens fitting, during which parameters are often modified, early toxic or allergic reactions are identified and patients are adapting to lens wear. Late aftercare includes 6-month and annual progress evaluations, which assess contact lens effects on corneal shape and physiology. Lenses are reordered or replaced as needed. The late-aftercare visits are critical to evaluate the patient for signs of lens-induced pathology, such as papillary conjunctivitis, blepharoptosis, neovascularization, polymegethism, corneal warpage and refractive error change. All aftercare visits should assess the patient for compliance as well. Routine ophthalmic examinations also should be performed as necessary during the aftercare visit for conditions unrelated to lens wear.

This chapter will offer a measure of the standard of care required of an aftercare visit by highlighting the procedures and strategies that can be employed at every aftercare visit in order to investigate efficiently and accurately the contact-lens-wearing eye and arrive at the precise diagnosis if there are any problems. Occasionally, patients will present with complaints of poor vision, discomfort or red eyes. Ocular changes associated with such symptoms may or may not be detected by examining the eye and vision with standard clinical instruments such as the phoropter, slit-lamp biomicroscope and keratometer. If subclinical ocular changes are responsible for such lens-related complaints, they may be detected only using specific problem-solving strategies, and often with the use of advanced equipment. Therefore, strategies and advanced procedures used in the investigation of symptomatic as well as preclinical ocular changes associated with contact lens wear are also highlighted. Some instruments are found only in research and teaching institutions, but others are affordable enough to become part of the key devices that contact lens practitioners can add to their practices for routine pre- and postfitting care.

Recommended Visit Schedules

Aftercare schedules will vary based on lens type, mode of wear and underlying corneal physiology. For example, patients wearing rigid lenses should be examined more frequently during the first few months of lens wear. Patients using lenses for extended wear must be monitored more frequently; with the initial visits in the early morning – especially for rigid lens overnight wear – to assess lens adherence (Fig. 39.1), excessive overnight corneal swelling or infiltrative responses.

Additionally, patients with corneal pathology such as keratoconus or corneal dystrophy, postkeratoplasty, post-refractive surgery or those using contact lenses for other therapeutic applications such as aphakia or high ametropia, and paediatric patients, generally require more frequent aftercare as part of their management compared with uncomplicated cosmetic lens wearers.

Table 39.1 lists the recommended schedule of visits based on lens type, modality or therapeutic requirement for contact lens wear. If lens replacements and modified parameters are provided within this time period, the clock starts over again for each lens dispensed.

These recommendations are based on a survey of the literature and common clinical practice, and are listed in reference to the suggested mode of lens wear.

Preparing for the Aftercare Visit

Certain preparations need to be made before the aftercare appointment. The previous record of the patient should be reviewed beforehand so that the practitioner can become familiar with the case history, anticipate any potential problems and devise an appropriate history-taking strategy. It is common practice that contact lens records for contact lens aftercare examinations are separate from the comprehensive examination encounter form, even within electronic medical record systems. Efficient electronic medical records for contact lens practices will include separate forms for entry of contact lens parameters tried during the fitting as well visual and fitting results of trial and historical lenses. For example, efficient electronic records will allow the entry of comprehensive trial lens parameters with resulting vision, overrefraction, and fitting data stored, with the option of a carry-forward of the dispensed trial lens parameters at the follow-up visits. Data from a contact lens fitting or follow-up appointment may be retained separate or merged with typical encounter forms. All aftercare evaluations should record the recommended postfitting procedures including care solutions dispensed, whether on paper or within electronic medical records. Electronic systems may be preprogrammed with macros of common lens wear and care instructions for ease of selection and entry into the signed encounter note.

Before acquiring any patient-abstracted information, it is critical to include some patient demographics and appointment information. Along with patient names and identification numbers, age is an important variable to document, as this will assist in identifying presbyopic symptoms. The appointment date as well as time should be recorded on paper records; this data will probably be automatically recorded within electronic medical record systems. Date and time entry allow more accurate postexamination reviews if adverse reactions are noted at a certain time of day. For example, orthokeratology or rigid lens extended-wear patients typically are required to have initial extended-wear progress checks within 2 hours of awakening to monitor for lens adherence. Silicone hydrogel wearers should have initial progress checks within the first 2–4 hours of lens insertion to document any asymptomatic corneal staining induced from unanticipated lens–solution interactions (Andrasko and Ryen, 2008). Daily-wear rigid lens patients are usually examined later in the day because lens-induced pathology is likely to become more evident the longer the lens is worn.

Expected parameters of contact lenses worn to the aftercare visit should be at hand; these are typically carried over from the previous visit. This strategy is not always accurate because patients can present wearing a previous pair of lenses, or lenses that have become switched between the eyes; however, it affords an important point of reference during case history and compliance review.

A recent survey of eye-care practitioners around the world was performed to gather current practices for anterior eye health recording within examination records, and secondarily to provide the contact lens practitioner with guidelines on best practice (Wolffsohn et al., 2015). The guidelines recommend: record which grading scale is used; always grade to one decimal place; record what you see live rather than based on how you intend to manage a condition; grade bulbar and limbal hyperaemia, limbal neovascularization, conjunctival papillary redness and roughness (in white light to assess coloration with fluorescein instilled to aid visualization of papillae/follicles), blepharitis, meibomian gland dysfunction, and sketch staining (both corneal and conjunctival) at every visit (Wolffsohn et al., 2015). They suggest that other anterior eye features be recorded or sketched only if they are remarkable, although one should always indicate the tissue that has been examined, even if there are negative findings.

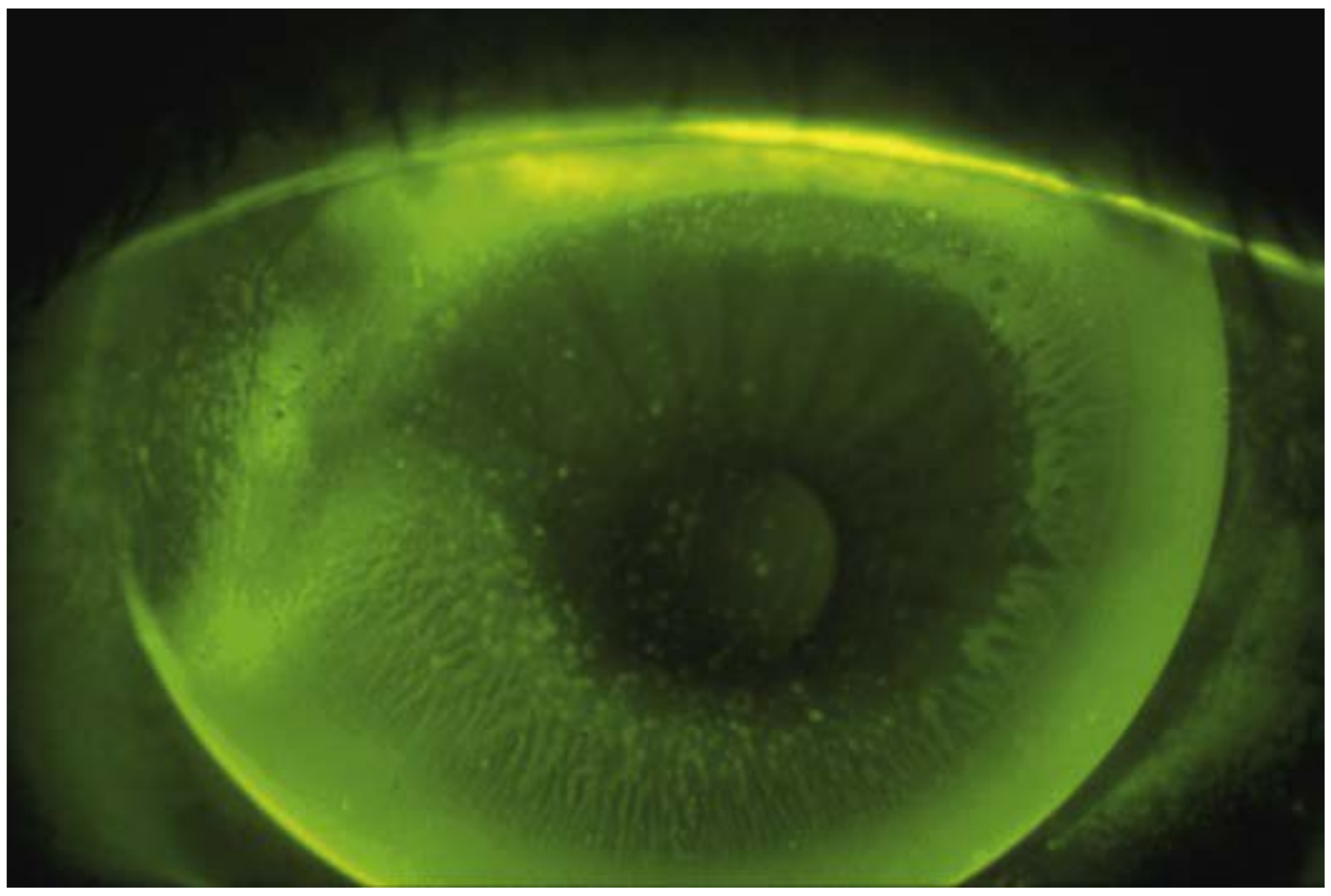


Fig. 39.1 Fluorescein reveals binding of a rigid lens to the cornea. This was observed in the morning following overnight lens wear. (Courtesy of Rolf Haberer, Bausch & Lomb Slide Library.)

Aftercare Procedures while Lenses are Worn

The general strategy adopted for aftercare visits is to consider the procedures in two phases: those conducted with the patient wearing lenses (assuming that the patient presents wearing lenses) and those conducted following lens removal. Certainly, patients should present to all aftercare visits while wearing lenses, unless a complication warrants lens discontinuation. It is also desirable that patients present towards the end of their lens replacement cycle (e.g. after having worn a pair of lenses for 2 weeks if on a 2-week lens replacement schedule). This will allow proper evaluation of the lenses and ocular response to the period of non-replaced lens wear.

It is rarely necessary to conduct all possible aftercare procedures at every follow-up visit. Essential procedures (such as those outlined below) generally should be performed; these can be supplemented with ancillary testing to solve specific problems. The aftercare visit may on occasions be very brief; for example, if a patient presents with a minor problem soon after having been given a full aftercare examination and the solution is straightforward, it may only be necessary to see the patient for a few minutes. The only caveat here is that, for medico-legal reasons, vision should always be measured if the patient enters the consulting room, no matter how brief the visit.

HISTORY TAKING

The case history is crucial to assess patient compliance and to begin to formulate an opinion about the cause of any possible contact-lens-related complications that have developed. The information obtained should include, at minimum, a subjective assessment of vision (including extent and duration of any morning or post-lens removal blur), comfort, wearing time and care regimen. Additionally, it is important to elicit symptoms such as redness, tearing, photophobia or discharge if they are present. In the early aftercare phase, these series of questions are imperative to establish whether there is an incompatibility with the solutions or lenses.

TABLE 39.1 Suggested Aftercare Schedules

Lens Type	Examine After:		Examine Every:		Rationale
	1 week	1 months	6 months	12 months	
Soft daily wear	☐			☐	Intrinsically safe
Rigid daily wear	☐	☐		☐	Increased risk of adverse events
Soft and rigid extended wear	☐	☐	☐		Increased risk of adverse events
Scleral	☐	☐	☐		Increased risk of adverse events
Therapeutic	☐	☐	☐		Compromised eyes

During the late aftercare phases – in addition to the above case history – it is good practice to review medications used by the patient and to ascertain whether any general allergic responses have been encountered, so as to ensure that these circumstances have not changed since the last visit. Additionally, patients can be invited to describe their chief complaint (if any) and review the overall lens-wearing history. A more detailed account of contact lens history taking can be found in Chapter 35.

VISUAL ACUITY

Presenting distance and near visual acuity with contact lenses should be recorded monocularly and binocularly with the consulting room lights on. This should be undertaken at each visit and the results compared with those expected from the dispensing visit or previous progress check. Visual acuity should be recorded prior to the utilization of any bright lights or disclosure dyes, which can induce lacrimation or lens misalignment.

OVERREFRACTION

As with any subjective refraction, initial objective assessment of refractive status using an autorefractor or retinoscope provides the starting point for the subjective overrefraction. Retinoscopy can also provide invaluable information when qualitatively viewing the red reflex over the lenses. Features such as optical zone edges or bifocal segments within the entrance pupil can be observed and correlated with patient complaints. Distortions or small visual obstructions induced from lens deposits, scratches, warped lenses or lens lift-off from the corneal surface may also be detected during overretinoscopy. Lastly, ocular pathology of new onset since the last visit, such as a posterior subcapsular cataract, can be easily detected by viewing the red reflex.

A subjective sphero-cylindrical refraction over the contact lenses is an important measure that should be recorded at every visit. At any aftercare visit, overrefraction can reveal required power changes due to unanticipated lacrimal lens formations, lens rotation, changes in refractive error, patient-induced lens power changes, lens warpage or lens flexure. The duochrome test is especially useful in determining the refractive end-point of an eye wearing a contact lens.

A useful clinical technique during subjective refraction is to obtain both spherical and sphero-cylindrical end-points independently (rather than merely calculating the best-sphere refraction from the sphero-cylindrical end-point). In cases of spherical lens fitting, spherical power modifications can be demonstrated to the patient and the resultant visual acuity measured. If vision is inadequate following a spherical overrefraction, a sphero-cylindrical overrefraction should be performed and a toric lens fit initiated if warranted. In soft toric or rigid front-surface toric lens fitting, a sphero-cylindrical overrefraction can assist in determining the magnitude and direction of any cylinder mislocation (Lindsay et al., 1997).

A repeatable cylindrical overrefraction obtained over a spherical rigid lens suggests lens flexure. Thin rigid lenses can flex approximately one-third of the corneal toricity. The probability of flexure increases with steeper and larger lenses. Flexure has been thought to increase with materials of higher oxygen permeability (Dk), but a study of rigid materials across a range of Dk values (from 15 to 151 Barrer) failed to find a difference in flexure when measured by overrefraction (Lin and Snyder, 1999). Flexure can be confirmed by manual or automated keratometry over the lenses. A cylindrical overrefraction over a back toric rigid lens results from a crossed-cylinder effect and careful review of the measured cylindrical power and axis suggests either over- or undercorrected cylindrical correction, misaligned cylinder axes or residual lenticular cylinder.

OVERKERATOMETRY

Corneal topography or keratometry performed while the lenses are worn will provide an index of lens flexure over a spherical rigid lens. As the anterior lens surface is being measured, the absolute instrument readings will not correlate with the baseline corneal measurements. The degree and location of detected cylinder should correlate with the overrefraction if lens flexure is the suspected cause of residual astigmatism over a spherical lens on a toric cornea.

Assessing lens surface topography is believed by some practitioners to be a useful aid in determining the lens–cornea relationship in soft lens fitting. When using keratometry, the clarity, consistency and shape of the mires that are reflected off the anterior soft lens surface can be useful for problem solving. For example, overkeratometry can help detect a steep or flat-fitting soft lens even though the lens fit may be judged to be clinically acceptable upon biomicroscopic examination. In a steep-fitting relationship, sustained overkeratometry observation can reveal distorted mires that become more irregular as the eye is left open between blinks. Additionally, the mire quality improves immediately after the blink when the lens has temporarily improved drapage over the cornea. In a flat fit, the opposite occurs: the mires blur immediately after blinking owing to excessive lens movement and the mire quality improves as the eye remains open and the lens stabilizes (Fig. 39.2).

EXTERNAL EXAMINATION

General inspection of the eye under an angle-poise lamp will reveal the presence of any general ocular pathology, such as red eye, conjunctival oedema or indeed almost any form of pathology, if severe enough. Also, evaluation of head posture, blink habits and palpebral aperture of the patient can provide important information on lens adaptation and lid effects. New rigid lens wearers often present with partial blinks or a narrowing of their palpebral aperture in an attempt to decrease lid sensations. Rigid contact lens wear has also been shown to induce true acquired non-senile blepharoptosis from mechanical manipulation of the eyelids, or mild contact-lens-induced lid inflammation (see Chapter 40).

SLIT-LAMP BIOMICROSCOPY

During the biomicroscopy evaluation while contact lenses are worn, the lens surface is first examined, followed by an evaluation of the lens fitting characteristics, and finally an assessment is made of possible interactions between the lens and eye.

Lens Surface Assessment

Both rigid and soft lenses should be inspected for surface quality, deposit formation, tear film interactions, and gross surface or edge defects. Clinically, it is very useful to observe the characteristics of the tear film and anterior lens surface between blinks. All soft lenses form mucoprotein deposits, which begin to form

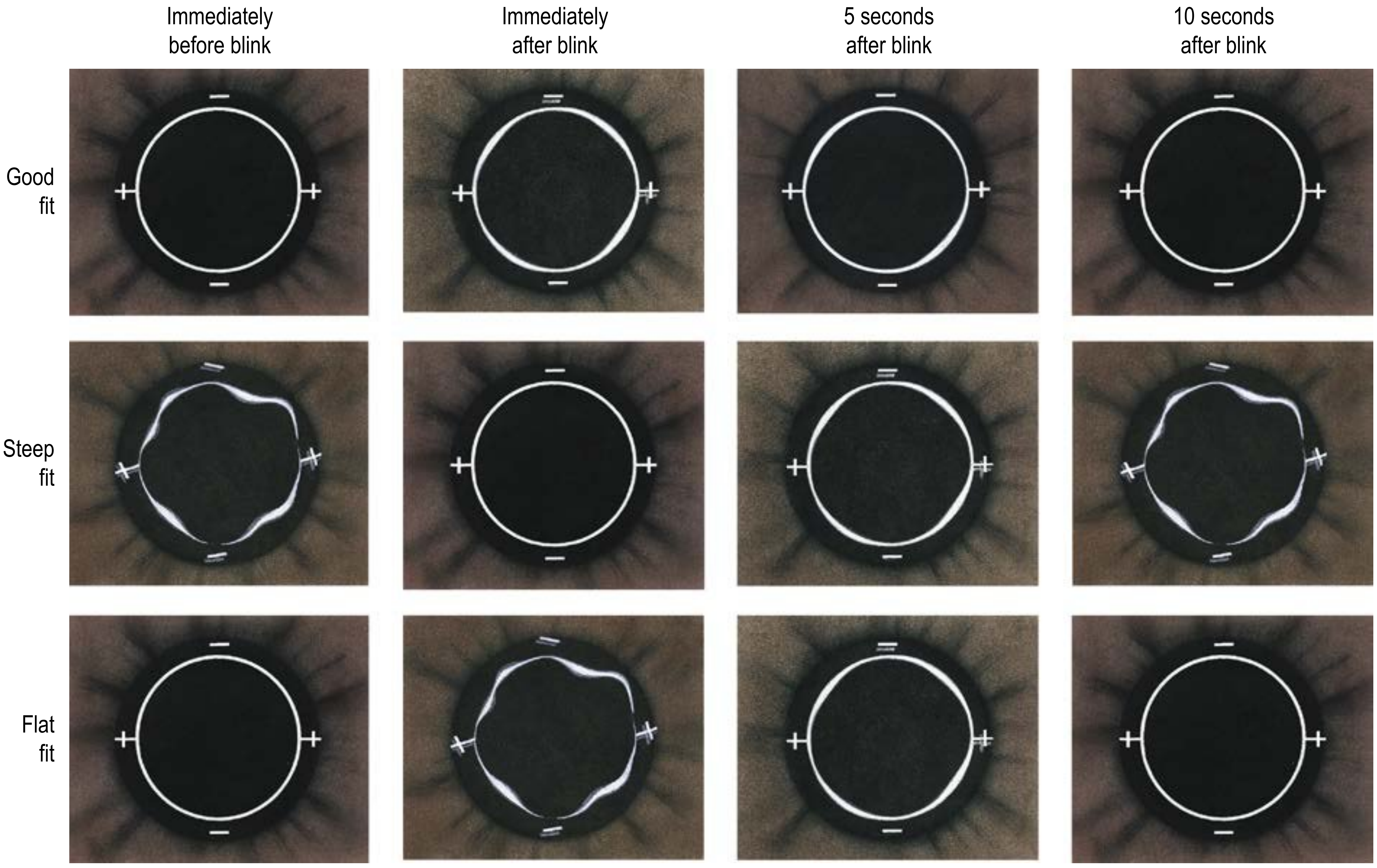


Fig. 39.2 Appearance of keratometer mires reflecting off the surface of good, steep- and flat-fitting lenses, observed immediately before a blink, and immediately, 5 seconds and 10 seconds after a blink.

as soon as the lens is inserted. Tear film constituent deposition and coating is also expected; however, the analysis at this stage is aimed at determining whether the specific lens–cornea interaction in the patient being examined has resulted in the formation of a biocompatible coating and, if it has, whether there has been any adverse reaction as a result. A decision can then be made as to whether the lens replacement frequency needs to be increased. Deposit formations have been discussed in Chapter 19, and usually indicate that more-frequent lens replacement, or a change of lens material, is necessary.

Although the majority of deposits on hydrogel lenses are mucoprotein, silicone hydrogel lenses may develop an incompatible lipid deposition. It is estimated that there are more than 45 individual lipids within the tear film and the chemistry of the relatively hydrophobic silicone hydrogel materials has resulted in clinicians needing to understand the deposition of lipids onto contact lenses and how they may best manage these interactions (Lorentz and Jones, 2007; Heynan et al., 2011). Thus, silicone hydrogel lenses should be closely observed for deposition even in the early refitting phase. Although these lenses deposit minimal amounts of protein (Suwala et al., 2007), about 13% of patients wearing silicone hydrogel lenses exhibit clinically significant lipid deposition on new lenses, even though they may not have had this problem with previous hydrogel materials (Nichols, 2006, 2013). Although some care products are specifically formulated for use with silicone hydrogel lenses, there are conflicting findings (depending on the care product formulation, lens substrate and research methods) with respect to care products that have the ability to alter lipid sorption appreciably (Zhao et al., 2009; Tam et al., 2014); however, adding a rubbing step removes a small amount of sorbed lipids (Tam et al., 2014).

Although it is clinically difficult to assess lens and tear film interactions, a biomicroscopy method for assessing tear break-up time using white light has been suggested. It is assumed that an intact and smooth tear film coating on the anterior surface of a lens (indicated by longer tear break-up times) enhances the biocompatibility of the lens and thus promotes comfort and tolerance. The patient is instructed to refrain from blinking and the examiner records the time to observe disruption of the tear film as evidenced by a disruption of the white-light specular reflex from the anterior lens surface. Generally, break-up times of greater than 5 seconds should be observed on clean or mildly coated lenses. Break-up times of 4 seconds or less are usually associated with visible deposits and may indicate that the lens should be replaced more regularly or that the lens material is incompatible with the ocular surface of the patient (Hart, 1987).

Obvious non-wetting of rigid lenses is easily detectable during the biomicroscopy evaluation and should correlate with patient symptoms of discomfort, hazy vision and the frequent need for lens removal and cleaning (Fig. 39.3). Non-wetting of rigid lenses is common in patients with meibomian gland dysfunction (MGD). Patients may have worn rigid lenses successfully for years, and used the same material and care products, yet find themselves with poor wetting lenses and difficulty managing comfort if the patient develops significant meibomian gland dysfunction. The international workshop on meibomian gland dysfunction (MGD) presented data suggesting that discomfort and dryness symptoms in contact lens wear are associated with MGD, and management of the MGD can improve the symptoms (Schaumberg et al., 2011). Managing MGD and non-wetting in rigid lens wearers with lid hygiene, care solutions and material selection is achievable but can be challenging; often patients have to switch to hydrogels or suspend

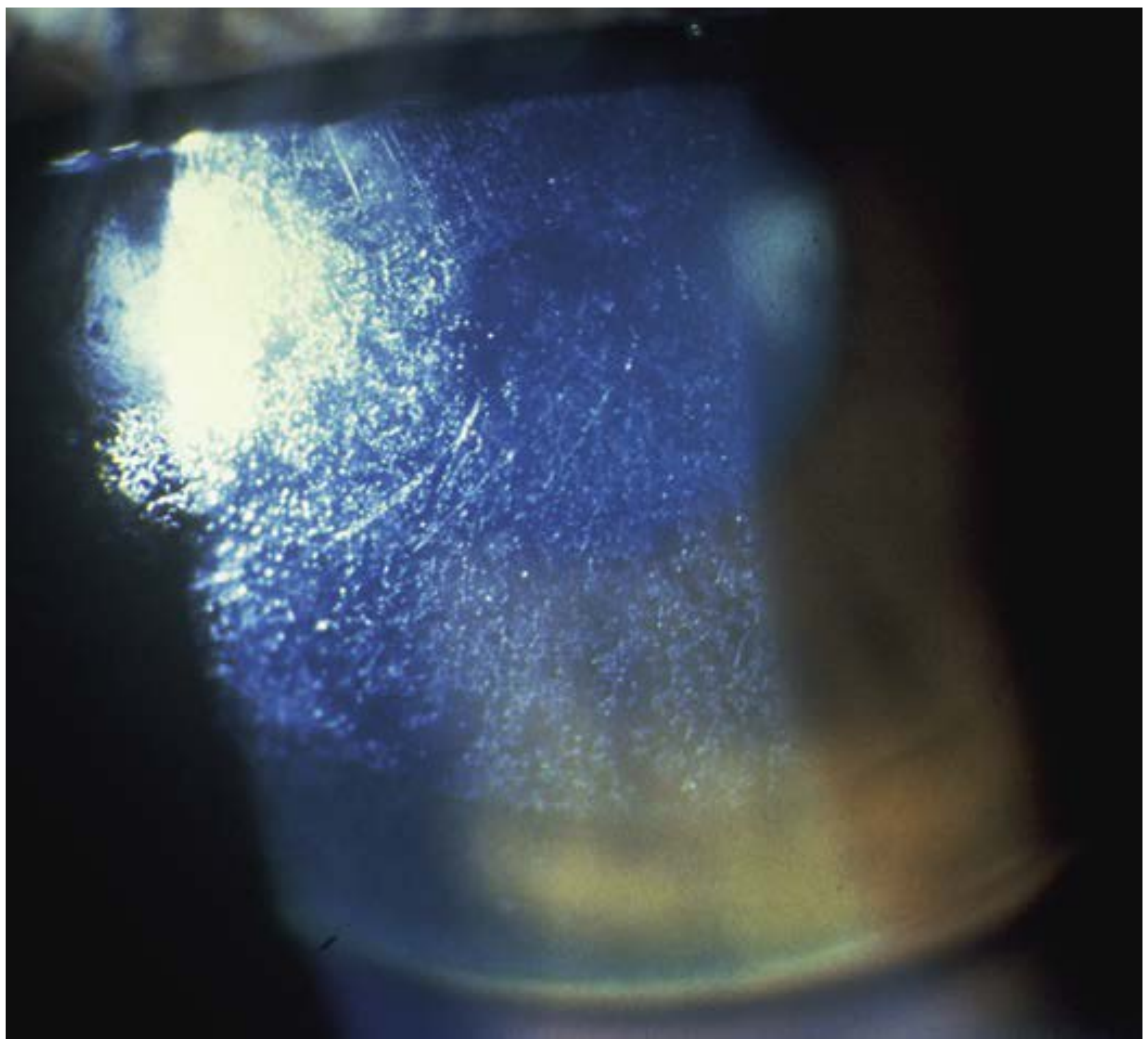


Fig. 39.3 Deposition on the surface of a rigid lens, presumed to be denatured protein. (Courtesy of Kathy Dumbleton, Bausch & Lomb Slide Library.)

lens wear if the deposition cannot be managed. Other cases of non-wetting detected in late aftercare visits may be secondary to organic compounds such as cosmetics or moisturizers, inappropriate lens care or adverse chemical interactions between incompatible solutions.

Rigid lens non-wetting is also occasionally noticed during lens dispensing; this immediate non-wetting is usually not related to MGD but may be due rather to improper preparation of the lens by the manufacturing laboratory that supplied the lens. Causes of manufacturing-related non-wetting include residual pitch and improper polishing.

Another lens surface change that should be assessed includes surface hazing. Symptoms caused by rigid lens surface hazing include lens dryness and variable vision; this problem is thought to be due to excess tear film evaporation from the anterior lens surface, resulting in surface drying. Surface hazing on rigid lenses in the early aftercare phases may be an indication to change the lens material. In general, silicone acrylate and fluorosilicone acrylate materials behave differently, with the latter exhibiting greater tear film retention. Lastly, surface scratches and calcified deposits are common on aged lenses. As lens polishing is not routinely practised in offices anymore, these findings typically dictate lens replacement.

Lens Fitting Characteristics

Lens movement and centration should be evaluated as described in Chapters 8 and 15 for soft and rigid lenses, respectively. Deviations from the initially desired fitting approach should be assessed and changes made to lens parameters as needed. However, practitioners should anticipate the possibility of a slight alteration of in-eye hydrogel lens performance towards the end of each day, as the lens dehydrates (Efron et al., 1987). Lens fitting may also alter towards the end of the wearing cycle of reusable soft lenses. This is due to an 'ageing effect', whereby there is a gradual loss of water over the life of the lens (Morgan and Efron, 2000). This water loss can possibly alter the lens dimensions and have an impact on lens movement and comfort.

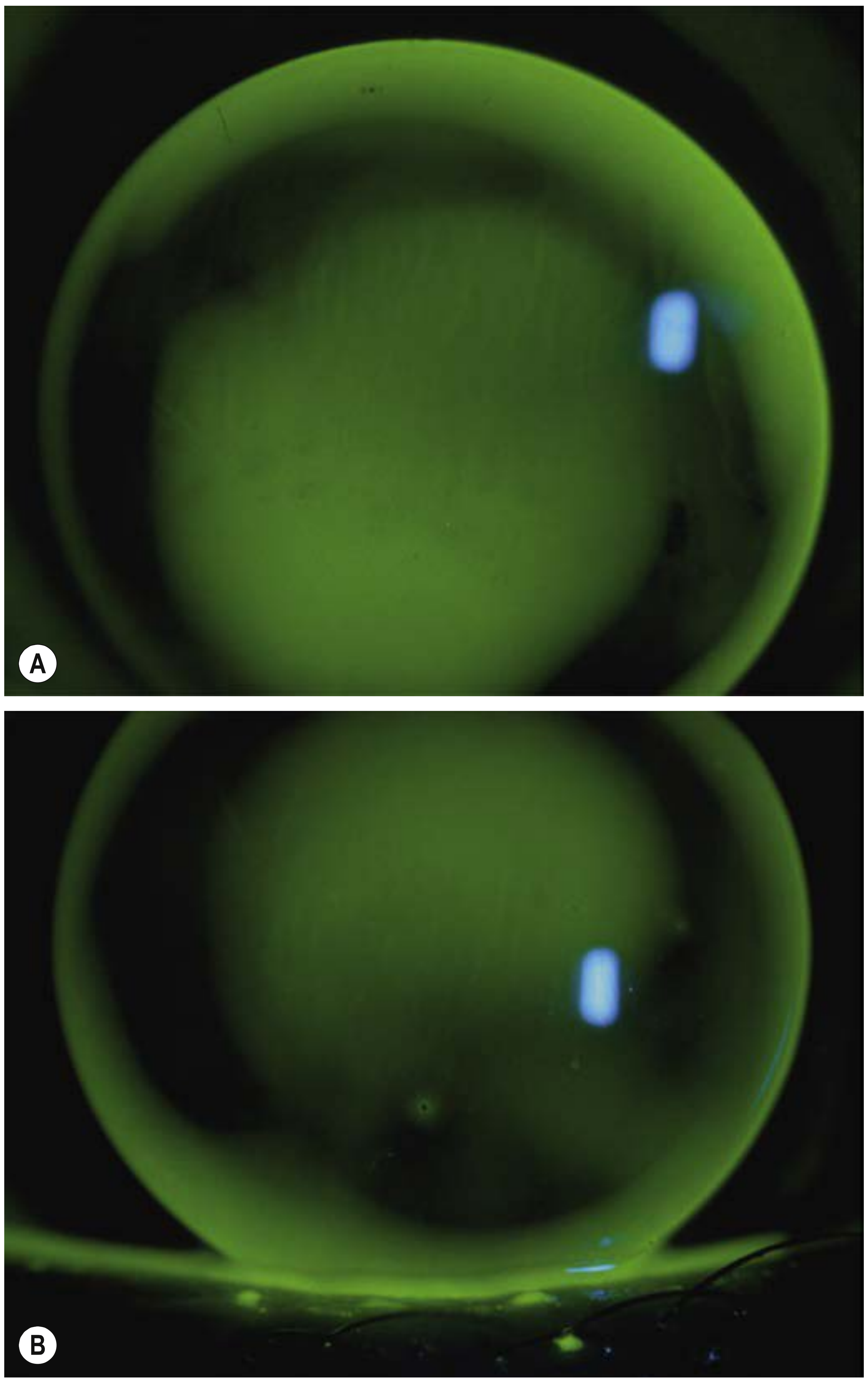


Fig. 39.4 (A) Rigid lens fluorescein pattern at initial lens dispensing, showing apical clearance. (B) Same patient and lens as in (A), seen at an aftercare visit 2 weeks later, after adapting somewhat to lens wear. Note that mild corneal touch is now evident; this may have been masked by excessive tearing during lens fitting.

For rigid lenses, a fluorescein pattern evaluation should always be performed, with either the Burton lamp or the slit-lamp biomicroscope, or both. It should be noted that with the Burton lamp it is not possible to observe the fluorescein patterns of rigid lenses made from materials that deliberately or inadvertently absorb ultraviolet light. When the slit-lamp biomicroscope is used, the appearance of the fluorescein pattern can be enhanced by introducing a cobalt blue filter into the illumination system and a yellow barrier filter (Wratten number 12 yellow) into the observation system.

The fluorescein pattern should be assessed at every routine rigid lens aftercare visit to establish whether the lens fit has changed. In the early aftercare phase, fluorescein pattern interpretations can vary as patients adapt to their lenses and reflex tearing subsides. It is not uncommon for a lens to be judged to be fit with apical clearance at a dispensing visit, yet be observed to be fit with apical touch at a progress evaluation (Fig. 39.4).

Scleral lenses should be assessed without fluorescein first to check for conjunctival blanching and post-tear lens thickness.

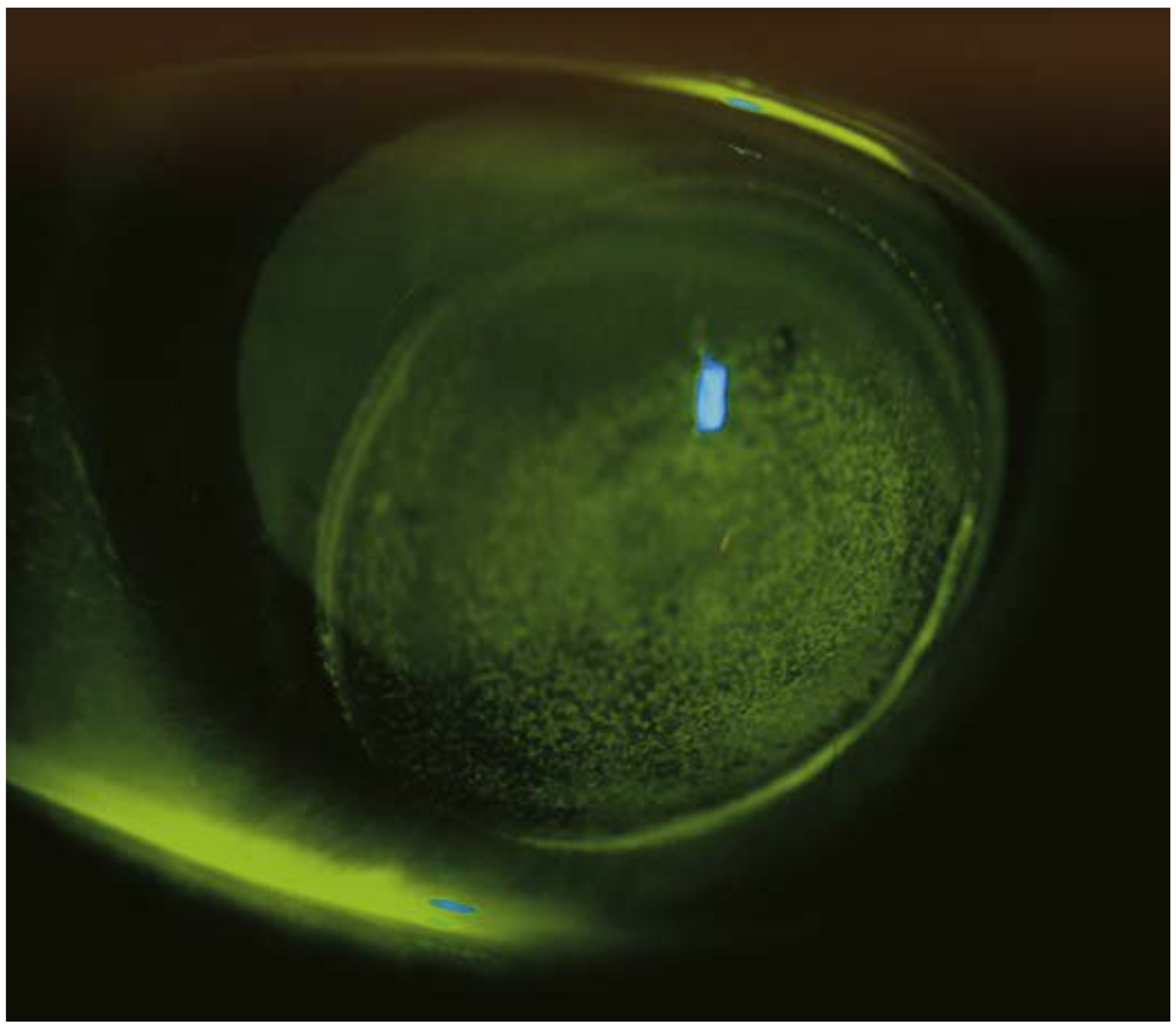


Fig. 39.5 Epithelial indentation ring immediately following lens removal, revealed with the aid of fluorescein, indicating an extremely steep-fitting lens and/or a strongly adherent lens.

The tear layer thickness can be assessed with a parallelopiped slit-lamp beam; the gap between the posterior lens surface and the anterior cornea can be judged in relation to the known corneal or lens thickness using white light. Fluorescein can then be added to assess tear exchange and flow beneath the lens surface.

Because corneal shape and posterior lens tear film thickness may change as the patient adapts to new lenses (which will influence the interpretation of the lens fit), it is wise not to alter lens parameters until the fitting has stabilized, typically about 2 weeks after lens fitting. Scleral lens settling is known to change the posterior tear film thickness dramatically once the patient has adapted (Kauffman et al., 2014). Over an 8-hour time span, lenses can settle by about 100 µm; therefore, lens changes made for tear clearance on the initial dispensing day may not be accurate. The lenses should be sufficiently settled after a few weeks, and then patients should present at least 2 hours after lens insertion for the aftercare visits.

Lens–eye Interactions

With the lens in the eye, there is an opportunity to look for any adverse interactions between the lens and ocular surface. In the case of 3 and 9 o'clock corneal staining, the tissue compromise would be expected to be aligned with the position of the lateral edges of a rigid lens. In the context of lens fitting, the peripheral profile of a rigid lens may appear steeper at a follow-up visit than was initially documented once reflex tearing has subsided; this can be detected by insufficient edge clearance, peripheral seal-off or even an epithelial indentation ring (Fig. 39.5).

A conjunctival indentation ring induced by a tight-fitting soft lens would be expected to coincide with the position of the lens circumference. Higher-modulus silicone hydrogel lenses may also create asymptomatic conjunctival imprints, circumferential conjunctival staining, or conjunctival flaps at the edge of the lens. Corneal staining induced by a lens defect is likely to be observed in the proximity of that defect. It would be difficult to reconcile many of the adverse reactions described above with lens performance and location if these reactions were first detected after the lens had been removed.

Aftercare Procedures Following Lens Removal

At this juncture, the lenses need to be removed from the eyes of the patient. Patients should be invited to remove their lenses so as to demonstrate what they would normally do in their habitual lens maintenance environment. This provides an opportunity to observe and evaluate attention to hygiene (e.g. handwashing prior to lens handling), lens-handling skills, appropriate solution usage and general compliance. Any improper or irregular procedures should be either raised at this point or noted for later discussion with the patient. A series of tests that parallel those performed with the patient wearing lenses can now be undertaken with the lenses removed.

UNCORRECTED VISION

An initial measure of uncorrected vision can be reconciled against the presenting visual acuity, the magnitude and nature of the refractive error and the subsequent subjective refraction. It should be noted that vision may be significantly degraded – beyond that attributable to uncorrected refractive error – during the first 15 minutes following lens removal. This is due to the fact that the tear layer is disrupted following lens removal, which can take about 15 minutes to recover (Faber et al., 1991).

REFRACTION

Contact-lens-induced alterations in corneal curvature can significantly alter the refractive error with associated changes in visual acuity. An autorefractor or retinoscope should be used initially to determine refractive status prior to undertaking a subjective refraction. Retinoscopy has the added advantage of facilitating direct observation of the optical quality of the eye, the detection of ocular aberrations or distortions induced by the contact lens. The refractive error should be expected to remain constant or to progress slowly over time, and should be unaffected by lens wear. Also, visual acuity should remain correctable to prefitting levels. Reduced visual acuity may signal the presence of ocular pathology or lens-induced warpage if it correlates with corneal curvature changes, as described later in this chapter. An average of a one-line decrease in best corrected visual acuity attributable to contact-lens-induced topographic abnormalities has been reported (Ruiz-Montenegro et al., 1993).

Specific refractive error changes have been documented with certain lens types and wearing schedules. Myopic progression associated with daily wear of hydrogel lenses with low oxygen permeability was reported in early clinical trials (Barnett and Rengstorff, 1977). An average of 0.30 D increase in myopia has been reported after 9 months of extended wear of low-Dk soft lenses, which is presumably due to hypoxia-driven corneal oedema (Binder, 1983; Dumbleton et al., 1999). Conversely, extended wear with high-modulus silicone hydrogel materials has no impact on refractive error, and may even be associated with a hyperopic shift from central corneal flattening in some patients (Dumbleton et al., 1999). In fact, orthokeratology-like induced topographic changes have been documented with high-modulus silicone hydrogel lenses that are typically of high powers and/or being worn inside out (Szczotka-Flynn, 2004; Caroline and Andre, 2005).

Refractive error changes have been reported in adult patients who have monocular blur intentionally induced with monovision contact lens correction. Specifically, studies show that approximately one-third of patients can expect changes in anisometropia between 0.50 and 1.25 D after wearing monovision contact lenses (Wick and Westin, 1999).

KERATOMETRY AND CORNEAL TOPOGRAPHY

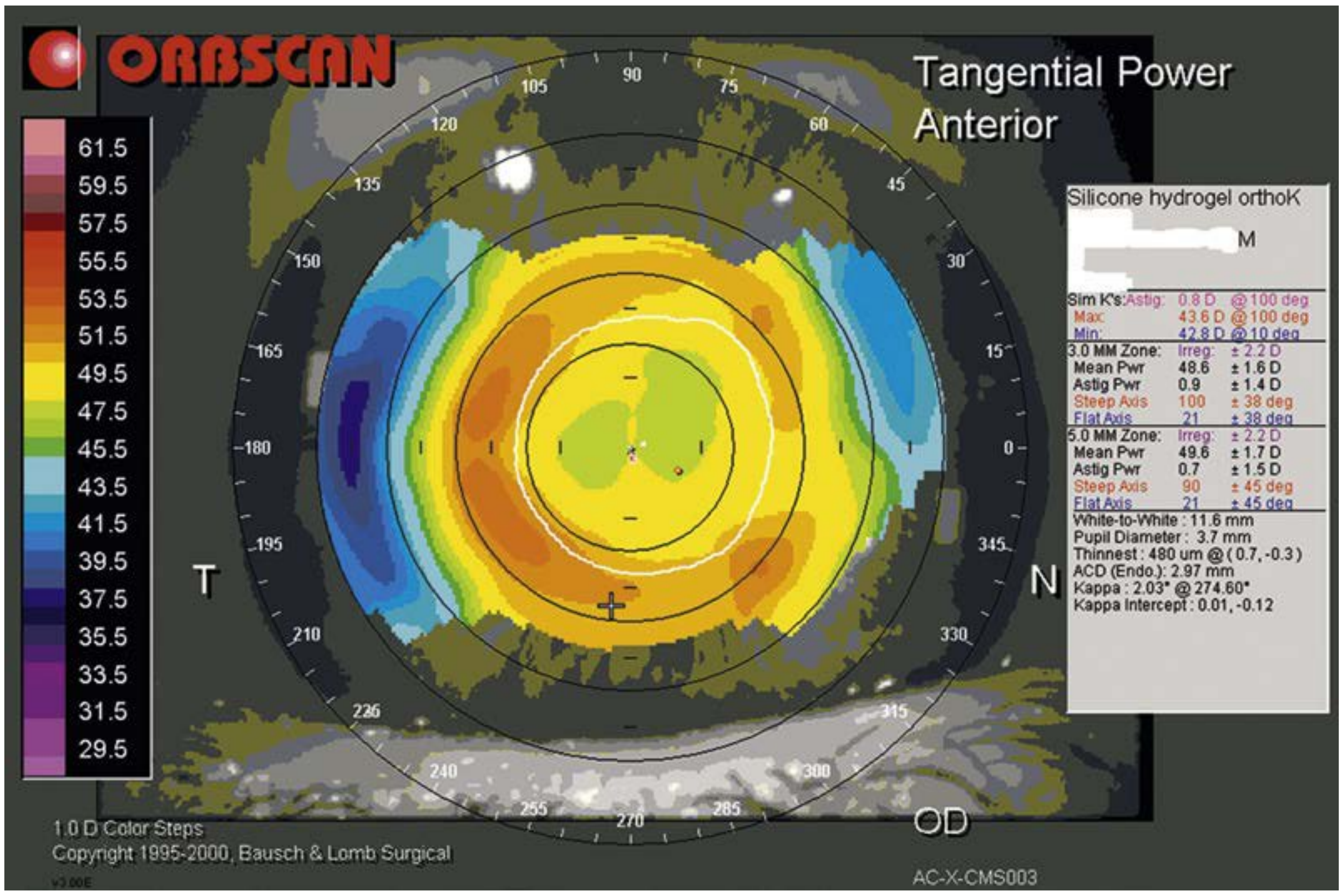
Corneal shape changes and/or warpage may appear with any type of contact lens secondary to mechanical stress or lens interference with corneal metabolism (Holden et al., 1985a; Wilson et al., 1990; Ruiz-Montenegro et al., 1993; Smolek et al., 1994; Sarzynski et al., 1997). It is important to be able to identify these corneal changes correctly before they create severe visual consequences. Also, careful corneal curvature assessment is a good predictor of lens fit and physiology. Corneal topography or keratometry may reveal numerical changes from the prefitting values, or an increase or decrease in corneal astigmatism. A general consensus is that, in normal eyes, changes greater than ±1.00 D from baseline are clinically significant, and in such cases the fit should be investigated for potential alteration to prevent potentially long-term corneal moulding. In eyes with pathology such as keratoconus or post-corneal transplantation, large changes in keratometry readings are not uncommon. Increased corneal astigmatism or curvature changes in keratoconus indicate progression of the disease, and in post-corneal transplant patients indicate continued wound healing, recurrent disease (if the transplant was performed for keratoconus), or instability of the host cornea. Large changes in corneal astigmatism can be detected in keratoconus patients post-transplant, beginning about a decade after surgery (Szczotka-Flynn et al., 2004); therefore, continued measurement of keratometry or topography is prudent in these patients. Keratometry can detect surface irregularity by assessment of mire distortion. In fact, the quality of the mires should be graded at every progress check (see Appendix K).

A better technique to assess changes in corneal curvature is corneal topography. One of the most valuable applications of this technology is to monitor the stability of the cornea after both short- and long-term lens wear. Subtle corneal steepening or sphericalization that is undetectable with keratometry may characterize early corneal changes due to contact lens wear. Serial topography and topographic difference maps may reveal slight changes over time.

Occasionally, contact lenses can distort the corneal surface, resulting in transient or permanent corneal warpage. Most forms of distortion can be traced back to the fit and/or material of the lens. Different forms of corneal distortion can be detected, and often can be classified into one of three categories: (1) a shift from a prolate to an oblate shape, (2) inferior corneal steepening, or (3) 'smile' impression arcs.

Oblate Shape

The normal cornea is a prolate shape: it is steeper in the centre and flattens aspherically in the periphery. Long-term flat-fitting lenses can permanently shift the cornea to an oblate shape by flattening the central cornea and secondarily steepening the periphery. This type of warpage may not be detected with keratometry or manifest refraction if the astigmatism is regular and the patient remains correctable to 6/6. Only corneal topography can reveal the oblate shape, which can create difficulty in rigid lens fitting and problem solving. As mentioned previously, silicone hydrogel lenses can induce a transient oblate corneal shape and a related decrease of myopia. Fig. 39.6 shows an example of this phenomenon where a high



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Silicone hydrogel orthoK
[redacted] M
Sim K's:Astig:  0.8 D   @ 100 deg
  Max:          43.6 D  @ 100 deg
  Min:          42.8 D  @ 10 deg
3.0 MM Zone:    Irreg:  ± 2.2 D
 Mean Pwr       48.6    ± 1.6 D
 Astig Pwr      0.9     ± 1.4 D
 Steep Axis     100     ± 38 deg
 Flat Axis       21     ± 38 deg
5.0 MM Zone:    Irreg:  ± 2.2 D
 Mean Pwr       49.6    ± 1.7 D
 Astig Pwr      0.7     ± 1.5 D
 Steep Axis      90     ± 45 deg
 Flat Axis       21     ± 45 deg
 White-to-White : 11.6 mm
 Pupil Diameter :  3.7 mm
 Thinnest : 480 um @ ( 0.7, -0.3 )
 ACD (Endo.): 2.97 mm
 Kappa : 2.03° @ 274.60°
 Kappa Intercept : 0.01, -0.12
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Fig. 39.6 Oblate corneal shape induced unintentionally in a lotrafilcon A extended-wear contact lens user.

myope wore a high-modulus silicone hydrogel lens for 30-day continuous wear, and 3 months after entering this mode of wear, central corneal flattening and 1 D of decreased myopia were detected.

Inferior Steepening

Long-term wear of polymethyl methacrylate (PMMA), low-Dk rigid lenses or superiorly decentred rigid lenses can cause inferior corneal steeping and give the appearance of keratoconus (Fig. 39.7).

Lebow and Grohe (1999) compared the topography findings of 100 eyes with either keratoconus or contact-lens-induced warpage. They concluded that keratoconic eyes have high shape factors, extremely high corneal irregularity measures and steep toric mean reference curvatures, whereas contact-lens-induced warpage is characterized by almost-spherical shape factors, elevated corneal irregularity measures and normal toric mean reference curvatures.

Even soft lenses can cause severe shape changes, which are often due to corneal hypoxia with secondary tissue swelling, and which can also give the appearance of inferior corneal steepening and pseudokeratoconus. Fig. 39.8A shows the topography of a patient after sleeping in group 4 hydrogel lenses on a weekly basis for 6 months. Note the inferior steepening, which mimics keratoconus. After discontinuing all lens wear, topography returned to normal in 3 weeks (Fig. 39.8B).

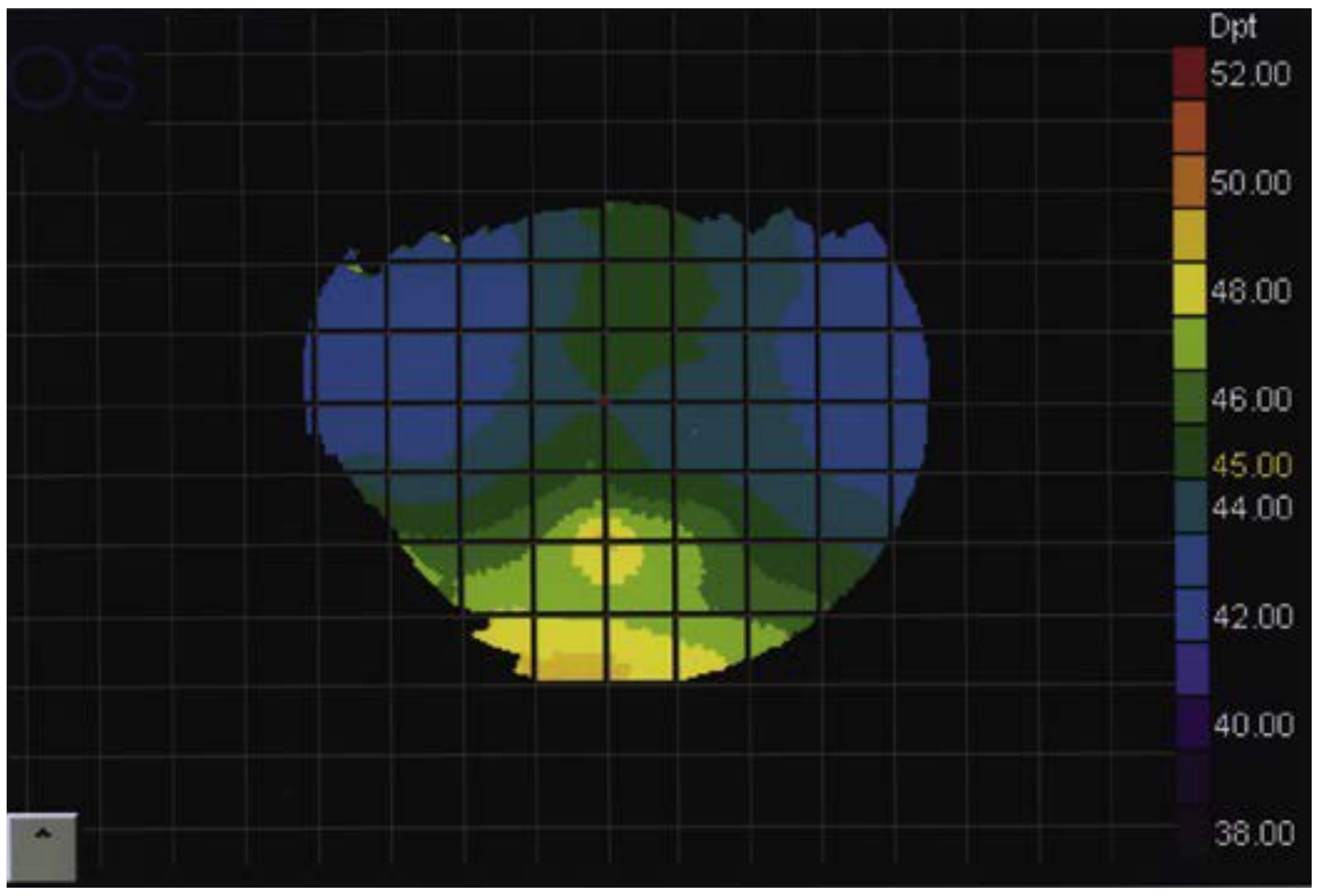


Fig. 39.7 Inferior corneal steepening secondary to corneal warpage from long-term rigid lens wear. (Courtesy of Leon Davids, Bausch & Lomb Slide Library.)

Impression Arcs

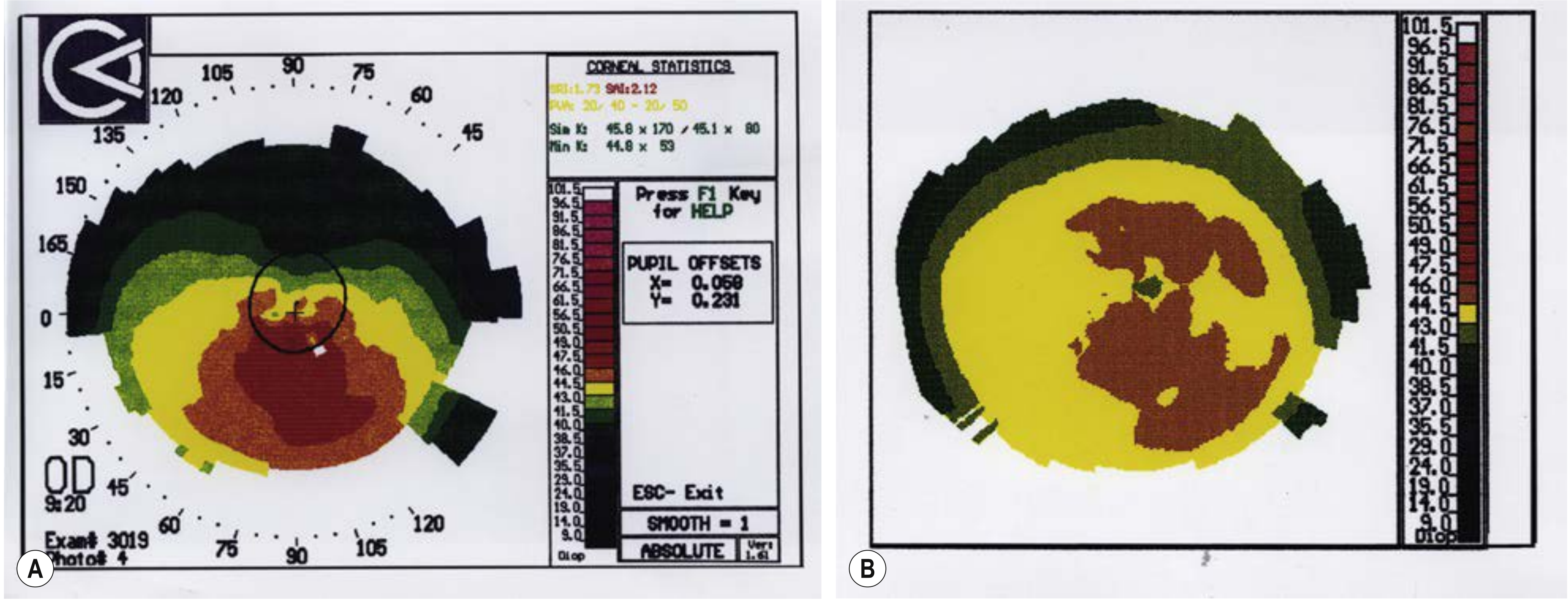
Rigid lens-induced arcuate corneal shape changes are most often located in the inferior third of the cornea and are commonly encountered if topography is routinely performed. These changes are referred to as 'smile' patterns because the resultant topographic plot gives the impression of a smiling face. In traditional rigid lens fitting, a flattened arcuate compression ring usually signifies unintended corneal moulding from the inferior edge of a superiorly decentred rigid lens. Just outside the lens edge, an arcuate zone of steepening appears (Fig. 39.9).

If the patient reports spectacle blur, this may suggest intermittent lens adhesion, and an attempt should be made to flatten the posterior curves for improved corneal stability. Difference maps are helpful in quantifying the amount of such lens-induced corneal changes (Fig. 39.10).

Once corneal warpage or clinically significant shape changes have been detected, the aftercare strategy should focus on adjusting the lens fit and monitoring the cornea for resolution. Soft lens-induced corneal curvature changes have been shown to stabilize between 6 and 18 weeks after discontinuing lens use (Sarzynski et al., 1997). In rigid lens-induced corneal warpage, up to 6 months may be required for a return to stable corneal topography (Calossi et al., 1996). If refitting a long-term PMMA contact lens wearer into rigid lenses, improved corneal health is be expected and spectacle-corrected acuity may improve, but the general topographic patterns of corneal warpage may not improve significantly (Novo et al., 1995).

Posterior Corneal Elevation

Corneal topography is widely recognized as the gold-standard method of measuring and following the cornea during contact lens fitting, especially with rigid lenses. Both Placido-based

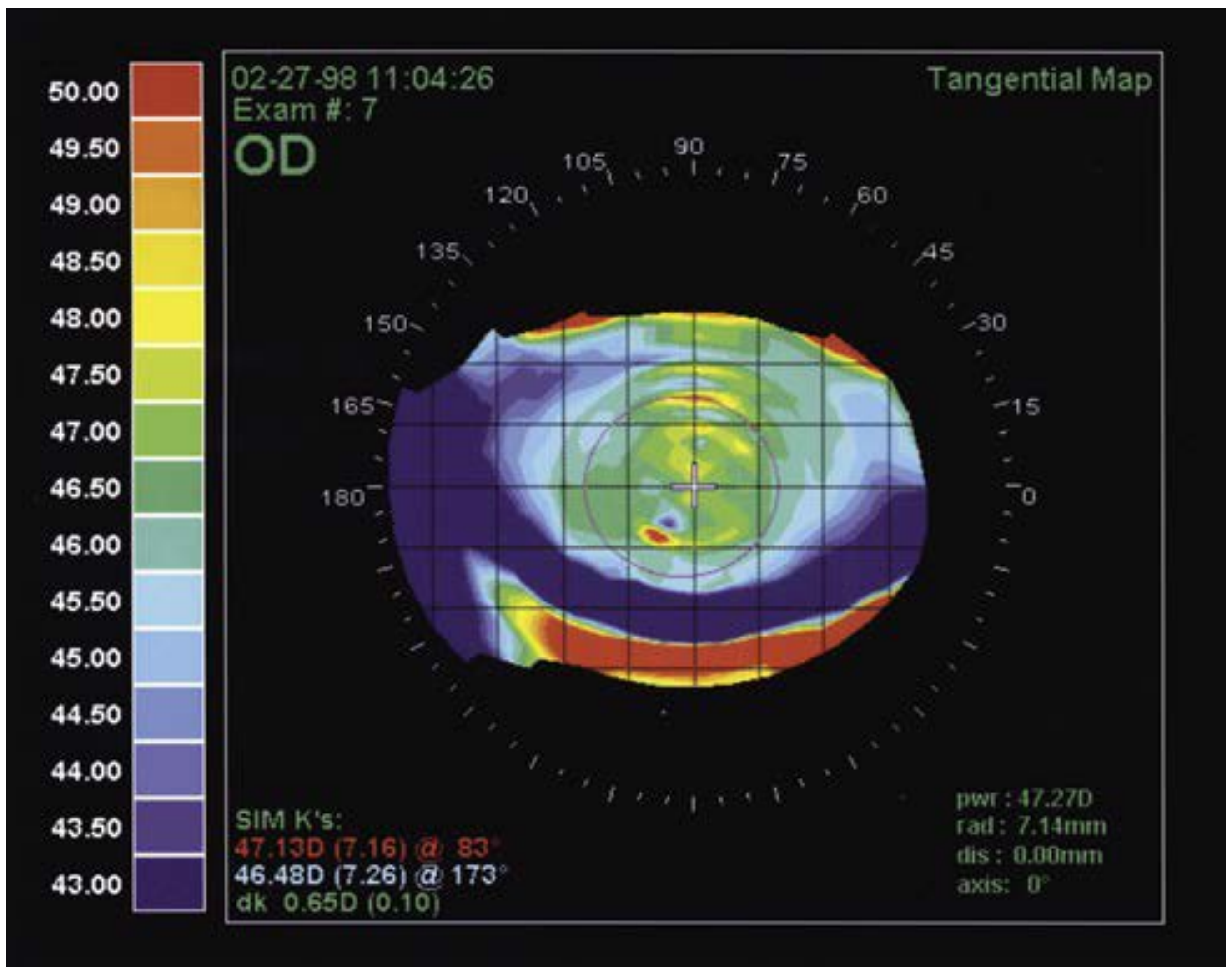

CORNEAL STATISTICS
SRI:1.73 SAI:2.12
PVA: 20/ 40 - 20/ 50
Sim K: 45.8 x 170 / 45.1 x 80
Min K: 44.8 x 53

PUPIL OFFSETS
X= 0.058
Y= 0.231

SMOOTH = 1
ABSOLUTE

Fig. 39.8 (A) Pseudokeratoconus pattern due to soft lens-induced hypoxia. (B) Same eye as represented in (A) after 3 weeks without lens wear; note the resolution of corneal distortion.

and Schiempflug systems that image the posterior corneal surface are routinely found in contact lens practices. Devices that can image the posterior corneal surface are efficient in their ability to screen for abnormally high posterior-surface elevation that would not have been detected with anterior-surface topography and provide corneal thickness across the measured image. Contact lenses can rarely alter the posterior corneal surface elevation; however, having access to posterior corneal curvature and elevations can help differentiate to early keratoconus, posterior keratoconus (Fig. 39.11) and postsurgical ectasia from other conditions causing decreased acuity that could not be detected with anterior-surface topography alone. Thus, in aftercare procedures, the best patients to utilize this instrumentation on are refractive surgery patients who have resumed contact lens wear and have a decrease in visual acuity (to screen for posterior corneal ectasia), and other patients who have decreased visual acuity that cannot be accounted for by any other pathology after a complete dilated exam has been performed.



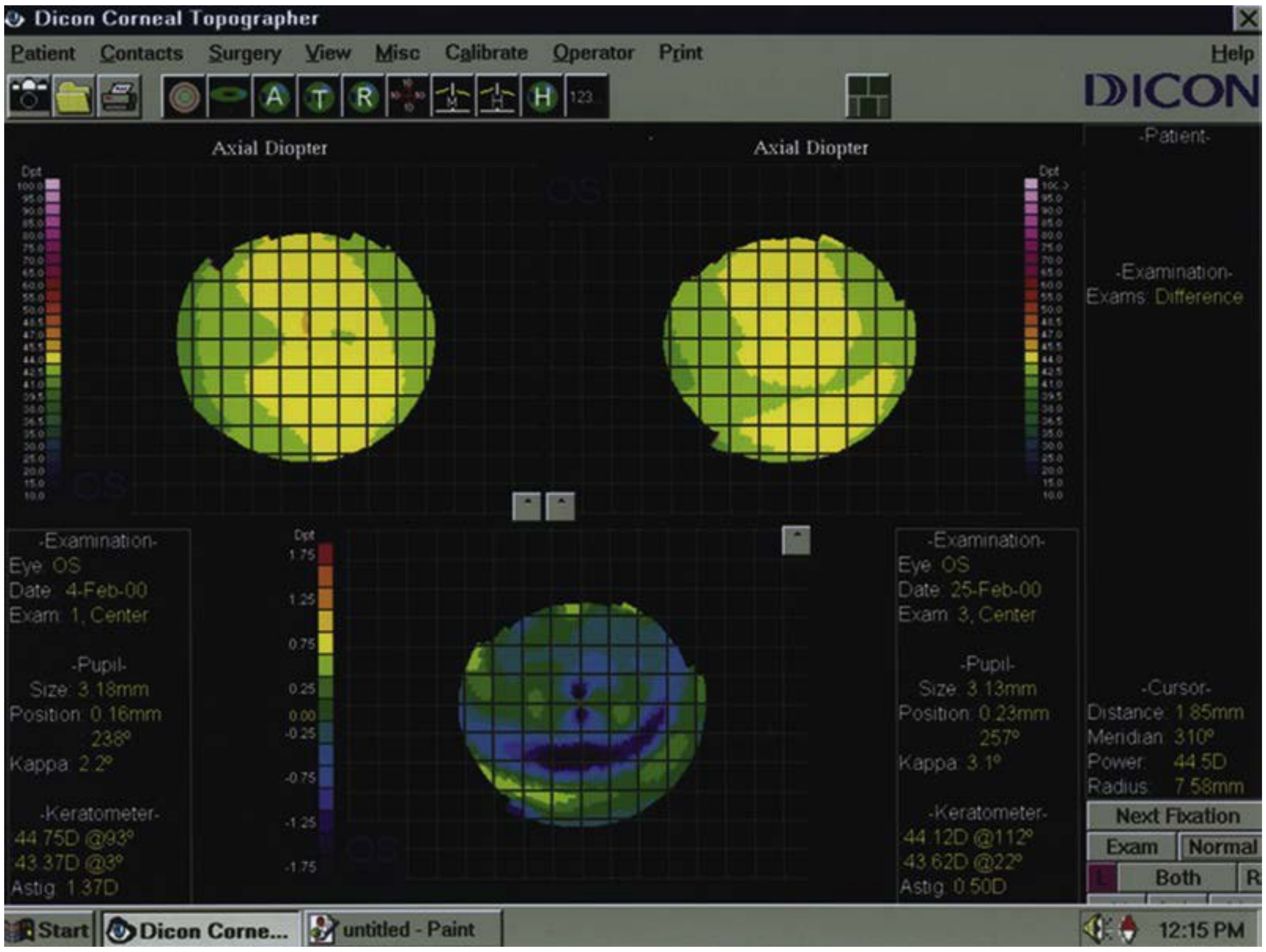
50.00
49.50
49.00
48.50
48.00
47.50
47.00
46.50
46.00
45.50
45.00
44.50
44.00
43.50
43.00
02-27-98 11:04:26
Exam #: 7
OD
Tangential Map
105
90
75
120
60
135
45
150
30
165
15
180
0
SIM K's:
47.13D (7.16) @ 83°
46.48D (7.26) @ 173°
dk 0.65D (0.10)
pwr : 47.27D
rad : 7.14mm
dis : 0.00mm
axis: 0°

Fig. 39.9 Inferior arcuate 'smile' corneal distortion caused by a decentred rigid lens.

Using the Orbscan instrument, the average amount of maximum posterior elevation is about 21–28 µm in non-diseased eyes. In a series of 140 normal eyes examined by Wei et al. (2006), the maximum posterior elevation was never greater than 46 µm. Therefore, if using the Orbscan instrument, a posterior elevation greater than 50 µm is clearly outside the normal range. Some feel that a posterior elevation greater than 40 µm, when coupled with positive findings on other topographic screening programmes, is a cause for concern (Rao et al., 2002). The Pentacam instrument differs from Orbscan and generally provides much lower values for posterior corneal elevation. If using this instrument, suggested cut-off points to delineate forme fruste KC range from 15.5 to 32.0 µm.

PACHYMETRY

Ultrasonic pachymetry is a common and quick method of obtaining the corneal thickness on a single point on the cornea. Ultrasonic pachymetry has the advantage of ease of use, allowing ancillary staff to operate the apparatus proficiently with only modest training. The small size of an ultrasonic pachymeter



Dicon Corneal Topographer
Patient
Contacts
Surgery
View
Misc
Calibrate
Operator
Print
Help
DICON
Axial Diopter
Axial Diopter
Dpt
-Patient-
Next Fixation
Exam
Normal
L
Both
R
Start
Dicon Corne...
untitled - Paint
12:15 PM

-Examination-
Exams: Difference

-Examination-
Eye: OS
Date: 4-Feb-00
Exam: 1, Center

-Pupil-
Size: 3.18mm
Position: 0.16mm
238°
Kappa: 2.2°

-Keratometer-
44.75D @93°
43.37D @3°
Astig: 1.37D

-Examination-
Eye: OS
Date: 25-Feb-00
Exam: 3, Center

-Pupil-
Size: 3.13mm
Position: 0.23mm
257°
Kappa: 3.1°

-Keratometer-
44.12D @112°
43.62D @22°
Astig: 0.50D

-Cursor-
Distance: 1.85mm
Meridian: 310°
Power: 44.5D
Radius: 7.58mm

Fig. 39.10 Topography difference map denoting the amount of corneal curvature change at an aftercare visit, which took place 3 weeks after dispensing a new rigid lens.

makes it portable and convenient. It is an applanation device that requires anaesthetic prior to use, therefore this test should be performed after the slit-lamp examination has been completed.

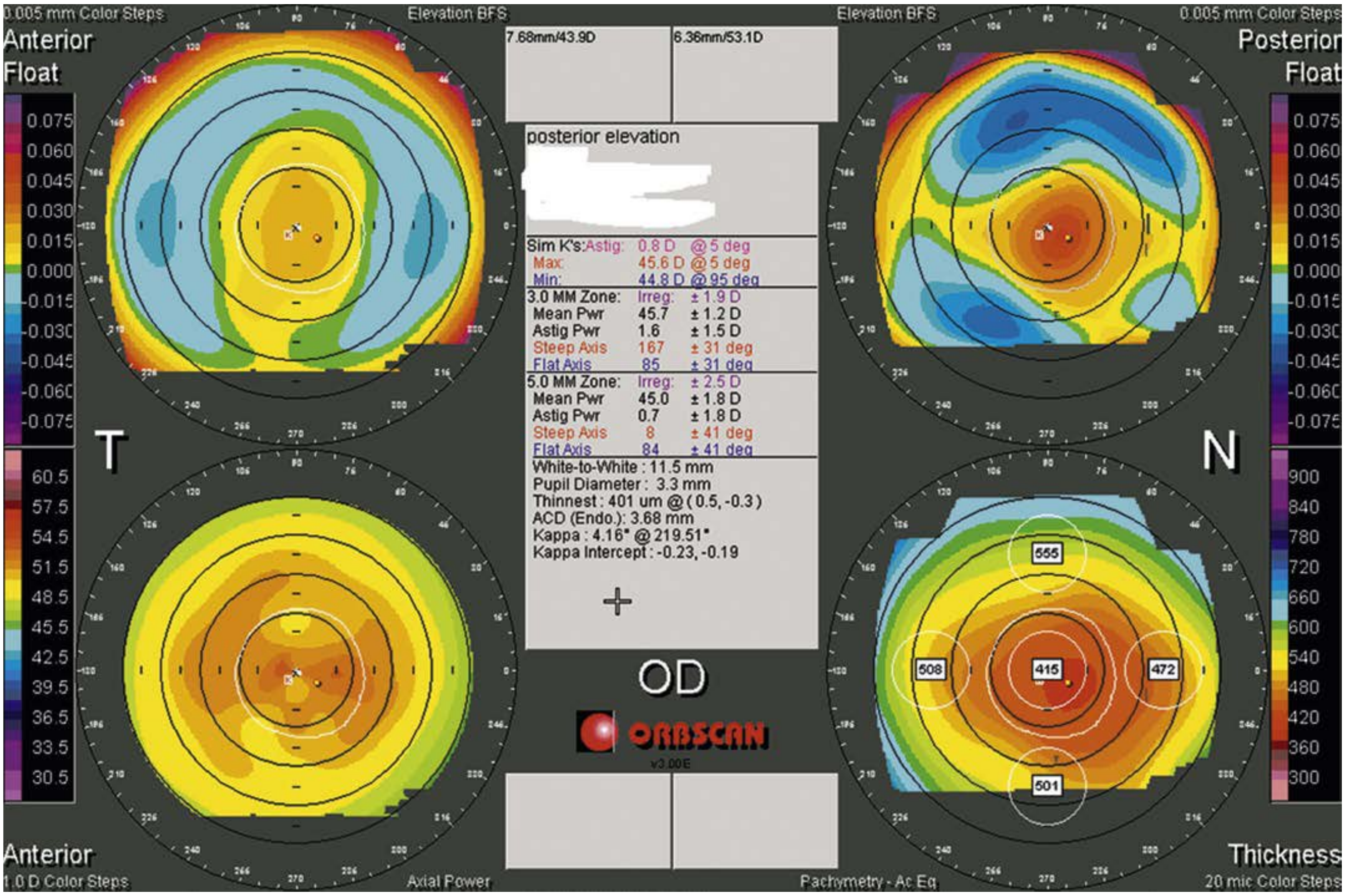
In the pre-silicone hydrogel lens era, one common application of the ultrasound pachymeter was to assess corneal swelling in extended-wear patients. It is a well-established finding that, with no lens wear, the cornea swells by an average of 2–4% overnight during sleep (eye closure). In extended wear with traditional hydrogel lenses, an average of about 10% corneal swelling has been documented. This instrument was therefore very beneficial in monitoring extended-wear patients wearing low-Dk lenses and, in fact, some practitioners used the corneal swelling response as an indicator of successful extended-wear candidates (Solomon, 1996). However, with the almost-exclusive use of silicone hydrogel lenses for extended wear currently, where very little corneal swelling has been documented, the use of pachymetry to monitor extended-wear patients has significantly diminished.

In specialty contact lens practices, monitoring corneal thickness is important and necessary for keratoconus and corneal transplant patients. In keratoconus, knowing the corneal thickness assists in determining which patients may be candidates for corneal collagen cross-linking. If the cornea is too thin, cross-linking may be contraindicated. Monitoring corneal thickness also assists in knowledge of the corneal thinning and progression of the disease over time. For corneal transplant patients, increased corneal thickness over time is an indication of either rejection (Larkin, 1994) or graft failure (Sugar, 2015). Global corneal thickness is easily provided from the Sheimpflug or slit-scanning-based elevation topography or anterior-segment optical coherence tomography (Fig. 39.12). However, clinicians should be aware that corneal thickness measurements are influenced by the method of measurement and that, although highly correlated, instruments such as ultrasound pachymetry, anterior-segment optical coherence tomography and topography should not be used interchangeably for the assessment of corneal thickness (Li et al., 2007).

SLIT-LAMP BIOMICROSCOPY

Biomicroscopy with fluorescein instillation and upper-lid eversion is essential at each aftercare visit. The clinical technique of slit-lamp biomicroscopy as it specifically applies to contact lens wear has been described in Chapter 37. The various ocular complications associated with contact lens wear are described in Chapter 40.

During each aftercare visit, a general anterior-segment examination should be performed and any significant findings carefully noted on the record card. The general anterior-segment examination includes an assessment of the lids and adnexa, conjunctiva, cornea, tear film, anterior chamber, iris



7.68mm/43.9D
6.36mm/53.1D

posterior elevation
[redacted]

Sim K's: Astig: 0.8 D @ 5 deg
Max: 45.6 D @ 5 deg
Min: 44.8 D @ 95 deg
3.0 MM Zone: Irreg: ± 1.9 D
Mean Pwr 45.7 ± 1.2 D
Astig Pwr 1.6 ± 1.5 D
Steep Axis 167 ± 31 deg
Flat Axis 85 ± 31 deg
5.0 MM Zone: Irreg: ± 2.5 D
Mean Pwr 45.0 ± 1.8 D
Astig Pwr 0.7 ± 1.8 D
Steep Axis 8 ± 41 deg
Flat Axis 84 ± 41 deg
White-to-White : 11.5 mm
Pupil Diameter : 3.3 mm
Thinnest : 401 um @ (0.5, -0.3)
ACD (Endo.): 3.68 mm
Kappa : 4.16° @ 219.51°
Kappa Intercept : -0.23, -0.19

Fig. 39.11 Abnormal posterior corneal elevation in an otherwise asymptomatic myopic contact lens wearer. The high posterior elevation results in central corneal thinning.

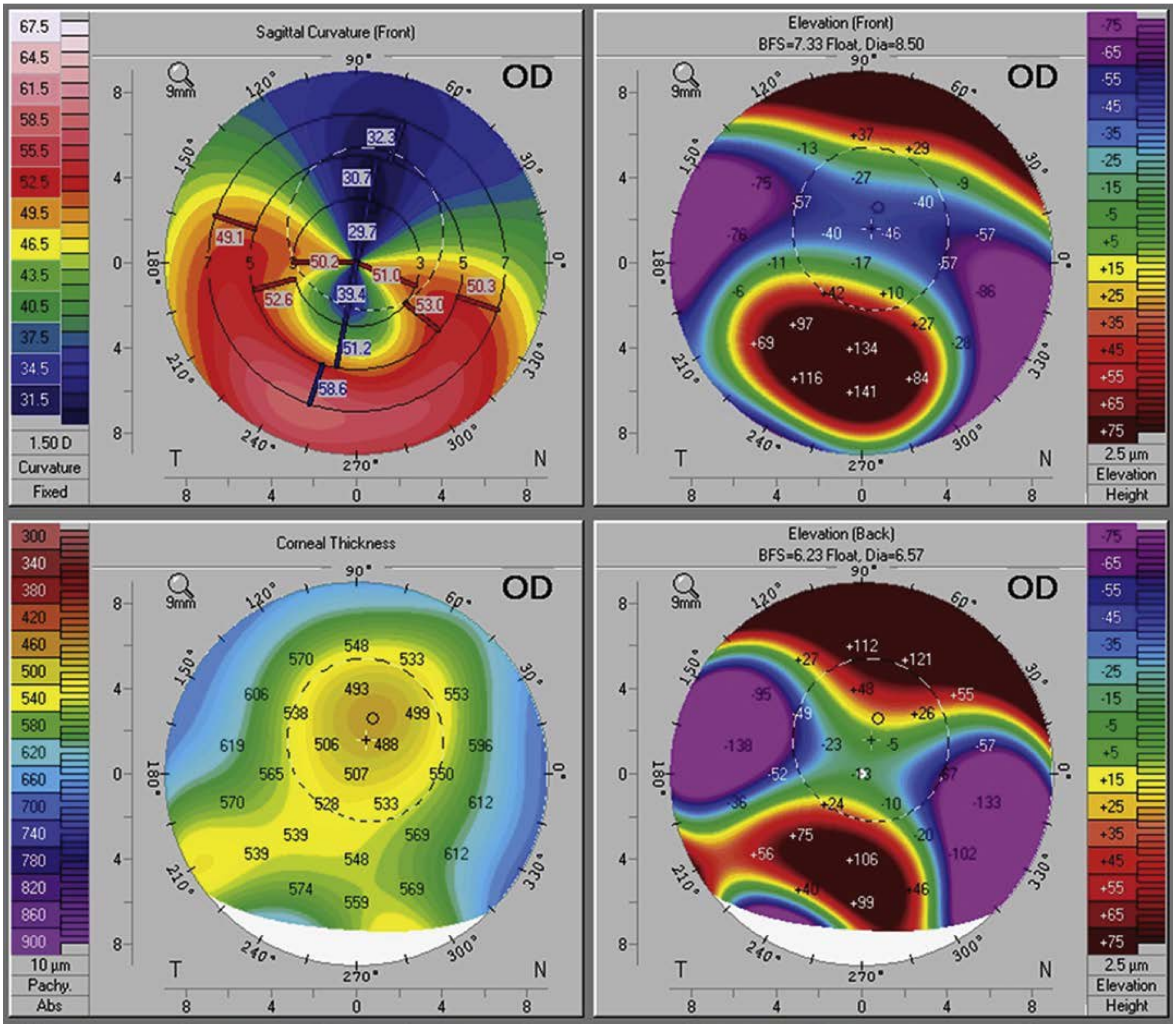


Fig. 39.12 Pentacam corneal thickness map in bottom left corner in patient with post-LASIK ectasia.

and lens. Additionally, the progress evaluation form should contain a clinical grade of the severity of any observed tissue change under evaluation (see section on Grading scales, below).

With silicone hydrogel lenses encompassing the majority of the contact lens market, it is important at this stage to screen for lens–solution incompatibility. This can be detected by the presence of corneal staining, as seen in Fig. 39.13. This so-called 'solution-induced corneal staining' (SICS) is most evident 2 hours after lens insertion in silicone hydrogel wearers who utilize a multipurpose solution (Jones et al., 2002; Garofalo et al., 2005; Andrasko and Ryen, 2008).

LENS INSPECTION AND VERIFICATION

Lens inspection and verification is an important final step of the aftercare visit. Lenses can be inspected using a 10× hand loupe or a binocular microscope. Alternatively, the lens can be retained using rubber-tipped tweezers and held in position adjacent to the brow rest of a slit-lamp biomicroscope. A broad beam is used to illuminate the lens, which is best viewed against a dark background.

The techniques of soft and rigid lens verification are described in Chapters 7 and 14, respectively. Rigid lens verification is important because these lenses can steepen or flatten with time and may be susceptible to warpage. An assessment made on a patient who – unknown to the practitioner – is wearing a distorted lens, may result in that practitioner reordering a lens of inappropriate parameters. Additionally, rigid lens power changes have been shown to be induced as a result of overzealous lens cleaning by patients. For example, increased minus power in rigid lenses can result from aggressive digital cleaning with abrasive cleaners on silicone acrylate lenses (O'Donnell, 1994; Woods and Efron, 1999). Soft lenses can also be verified in cases of suspected lens mix-up or to

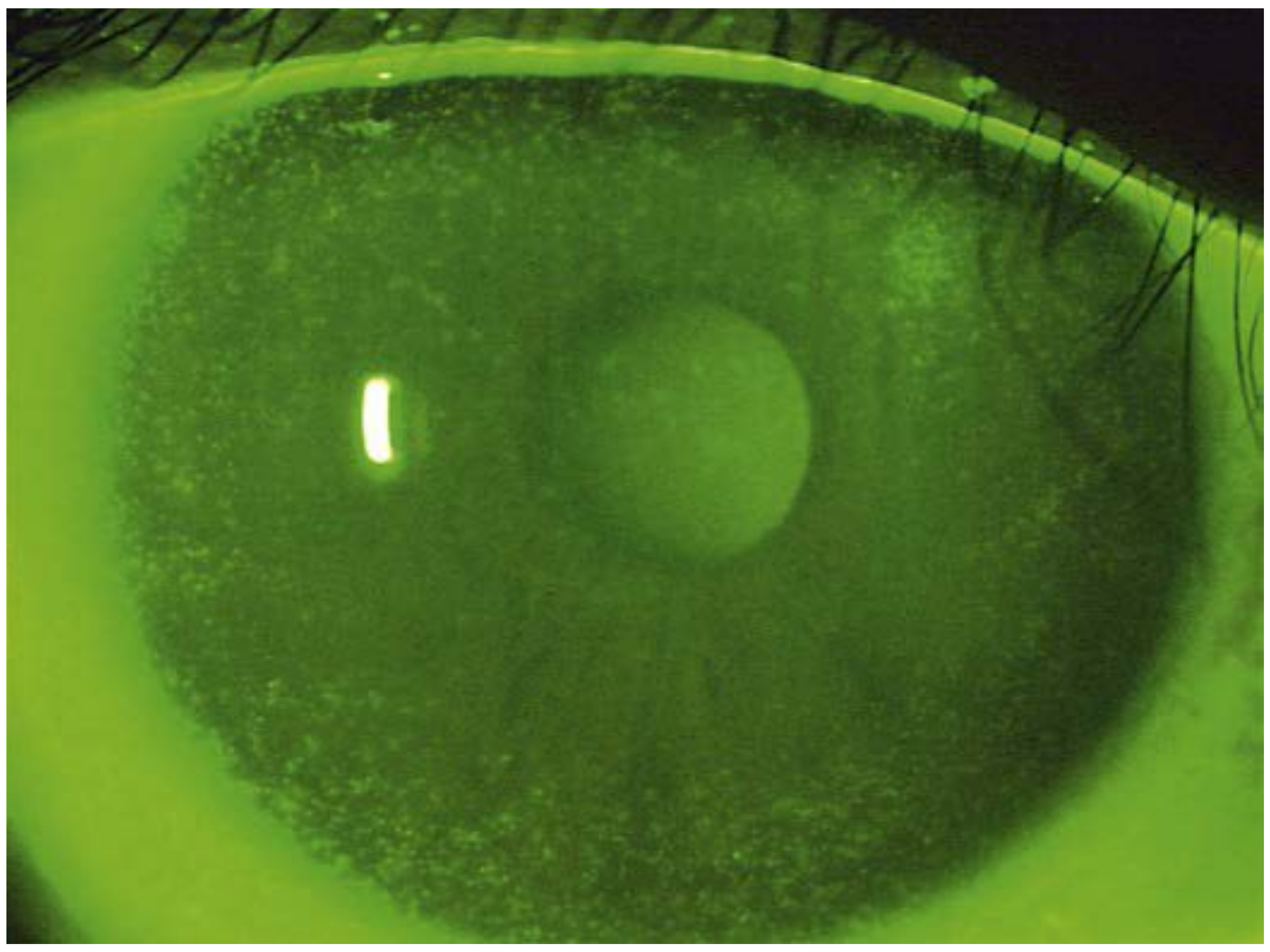


Fig. 39.13 Corneal staining in a silicone hydrogel lens wearer using a multipurpose cleaning and storage solution. (Courtesy of Suzanne Efron.)

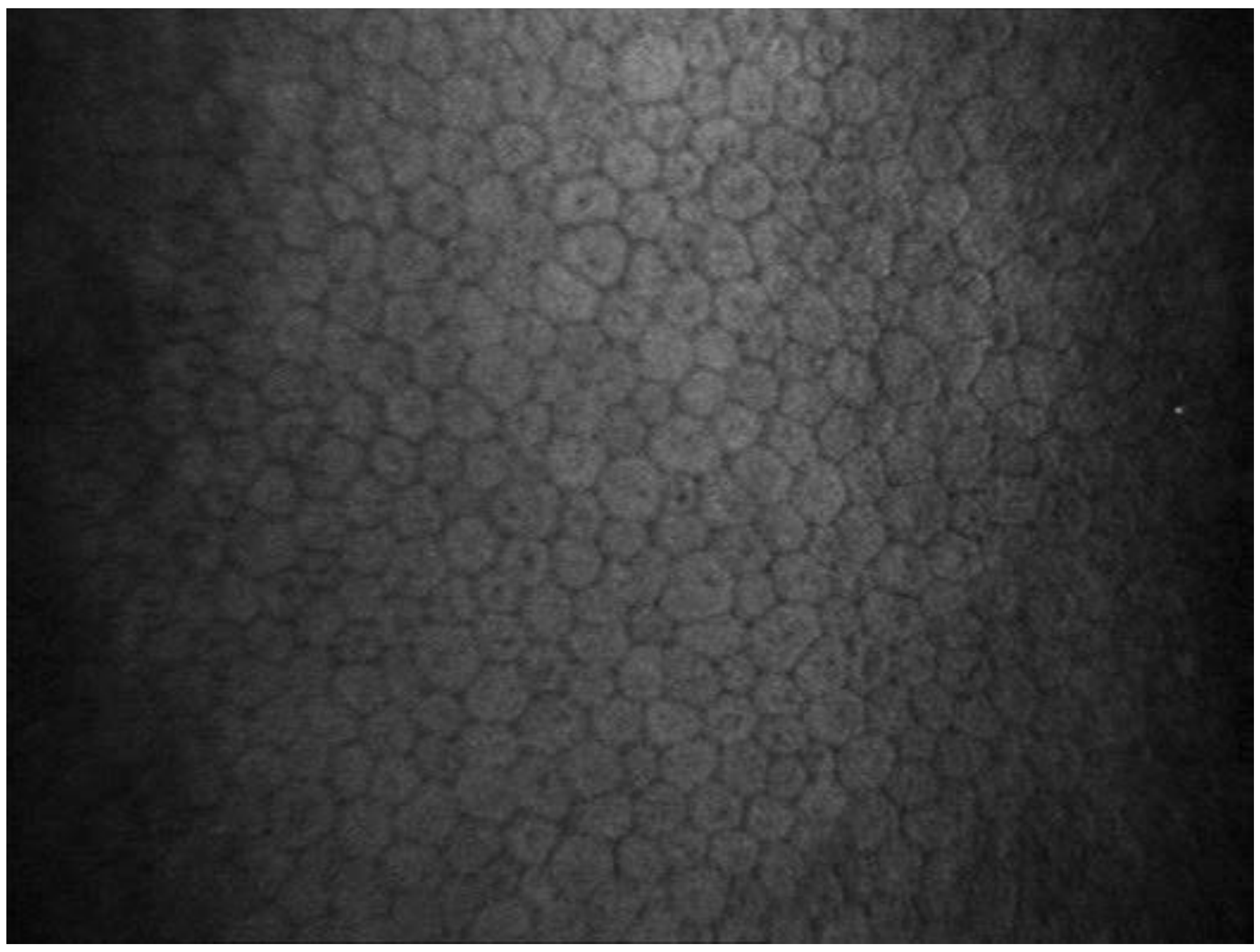


Fig. 39.14 Corneal endothelium as imaged on a Nidek confocal microscope.

characterize the key features of the lens of a patient who may be new to the practice.

ADDITIONAL PROCEDURES

Additional procedures, which may not be readily available to all contact lens clinicians, include endothelial specular microscopy, confocal microscopy, and anterior-segment optical coherence tomography (OCT). If available, these techniques afford valuable information that can have an impact on the management of contact lens patients at early and late aftercare visits. Digital slit-lamp imaging is a valuable method of recording clinical information; this technique is described in Chapter 41.

Corneal Endothelial Analysis

Specular microscopy is an in vivo technique of viewing the corneal endothelium. It is a standard method for determining cell loss or changes in cell size (polymegethism) or cell shape (pleomorphism) with ageing (Laing et al., 1976) and following contact lens wear (Carlson et al., 1988). In the contact lens practice, the major function of this device is to evaluate the short-term endothelial response ('blebs') (Holden et al., 1985b) and, more importantly, the long-term endothelial response to contact lens wear (polymegethism and pleomorphism, referenced to age-matched normals) (Carlson et al., 1988) during the aftercare visits. These endothelial responses to contact lens wear are described in Chapter 40.

Analysis of the endothelium is especially important in the corneal transplant patient. In penetrating keratoplasty patients, the mean endothelial cell density decreases 7.8% per year from 3 to 5 years after keratoplasty, compared with approximately 0.5% per year in unoperated normal corneas. Five years after surgery, the mean cell loss is about 60% of preoperative baseline donor values (Bourne et al., 1994). The analysis of endothelial cell densities after transplant, and during contact lens fitting of these patients, is important because low endothelial cell densities are significantly associated with increased corneal thickness and an increased risk of subsequent failure (Bourne et al., 1994). Low endothelial cell densities will also dictate using contact lenses with higher Dk/t values.

The corneal endothelium can be viewed with specular or confocal microscopy. In vivo confocal microscopy is a non-invasive way of examining the cornea. The basic principle of a confocal microscope is that a single point of tissue can be illuminated by a point light source and simultaneously imaged by a camera in the same plane. This produces an image with a very high resolution but virtually no field of view, owing to a single point of illumination and detection. To solve this problem, the instrument instantaneously illuminates and synchronously images a small region of tissue with thousands of tiny spots of light, which are reconstructed to create a usable field of view with high resolution and magnification. The result is that confocal microscopes provide an en face view of the structure being analysed (Masters and Bohnke, 2002; Efron, 2007; Patel and McGhee, 2007; Guthoff et al., 2009) Confocal microscopy is commonly used for analysing all the layers of the cornea, but provides an exceptional view of the endothelium compared with specular microscopy, especially on eyes that are difficult to image (Fig. 39.14). The confocal microscope can be used to measure corneal endothelial density and morphology, epithelial structure and reflectivity, subbasal nerve plexus morphology and stromal reflectivity and thickness. In other aspects of contact lens practice, confocal microscopy is beginning to be used to assess subclinical inflammatory cells in the cornea (Sindt et al., 2012; Villani et al., 2014; Alzahrani et al., 2016a), bulbar conjunctiva (Alzahrani et al., 2016a) and lid wiper (Alzahrani et al., 2016b) as an indication of preclinical inflammatory events.

Anterior-segment Optical Coherence Tomography (OCT)

In contact lens practice, anterior-segment optical coherence tomography (OCT) is useful for corneal pachymetry as mentioned above, but also to achieve cross-sectional analysis of the anterior segment. OCT is a non-invasive, high-resolution and high-speed imaging modality that has experienced rapid clinical growth. Modern anterior-segment OCT is capable of generating three-dimensional ocular surface maps of the cornea and sclera with potential application in contact lens fitting

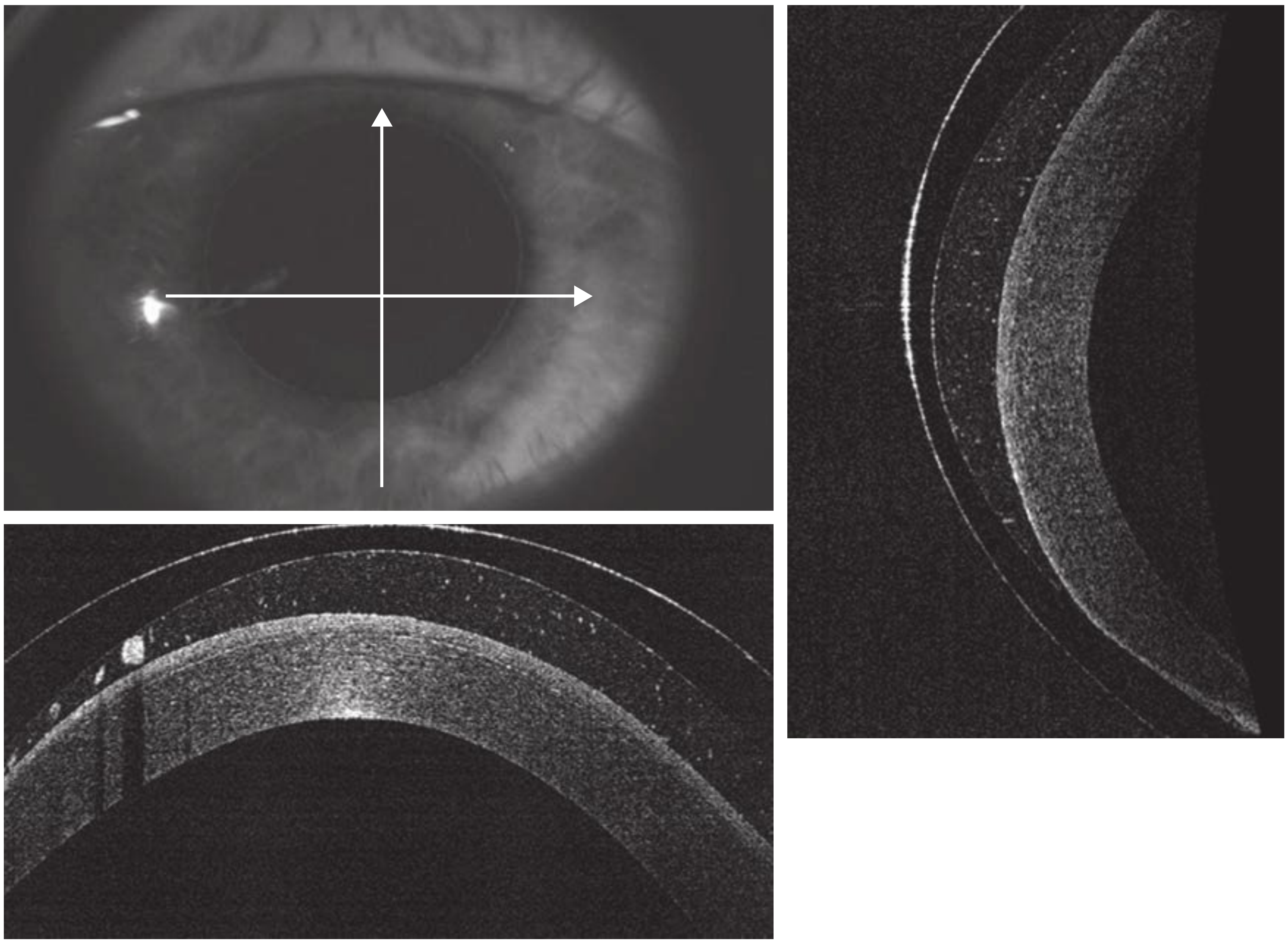


Fig. 39.15 Anterior-segment OCT of scleral lens on the cornea. Variable tear film thickness can be observed in the vertical and horizontal cross-section.

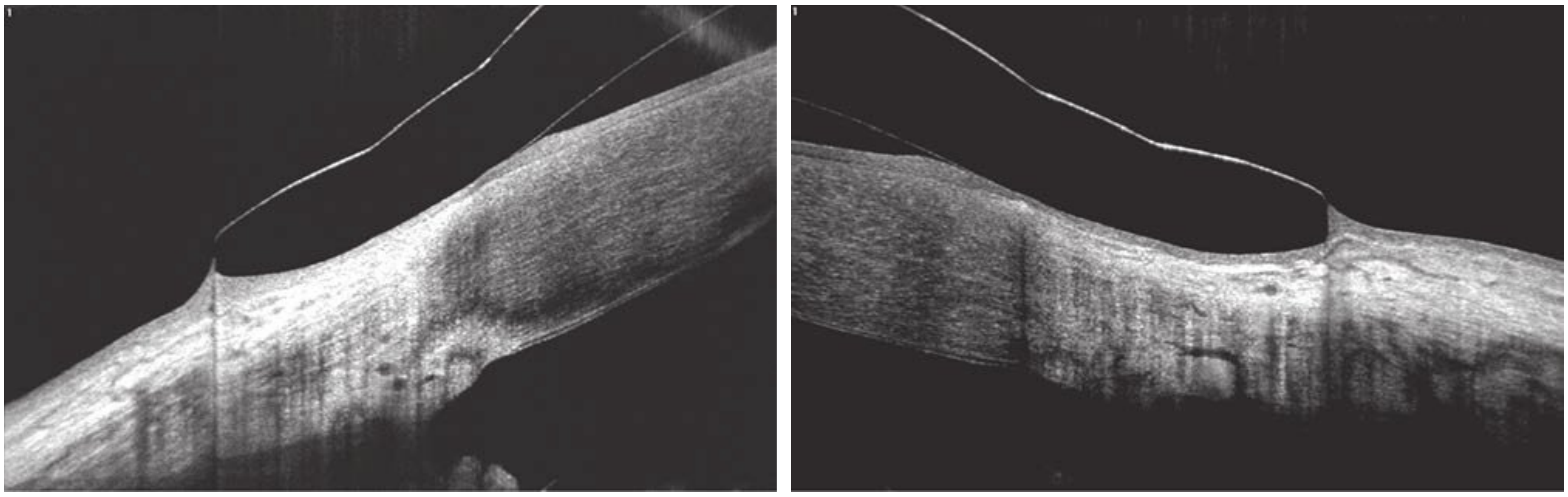


Fig. 39.16 Anterior-segment OCT image of peripheral scleral lens landing and conjunctival compression (on right).

(Luo and Jacobs, 2012). The most useful application is in the analysis of scleral lens conjunctival landing, as well as corneal and limbal clearance (Fig. 39.15). It allows precise calculations of the tear layer thickness, which may or may not be easily visible on slit-lamp examination. Peripheral landing and conjunctival compression can be easily assessed minutes after lens insertion, which may not be detectable clinically until hours after wear (Fig. 39.16).

Other Tests as Required

Although the patient may be presenting for an eye examination relating to contact lens wear, practitioners have an obligation to be cognizant of all possible causes of reported signs and symptoms, which on occasion may be unrelated to lens wear. If time is available, and / or the signs and symptoms are marked, it may be necessary to undertake a procedure that normally relates to a primary eye-care examination, such as visual fields, ophthalmoscopy, tonometry, gonioscopy, binocular vision assessment, corneal sensitivity, Tearscope evaluation and colour vision assessment. If, for whatever reason, these techniques cannot be undertaken at the time of the aftercare visit, another appointment should be made, or the patient should be referred for specialist attention, as appropriate.

Discussion with Patient

A critical aspect of the aftercare visit is the final discussion with the patient concerning the outcome of the consultation. The patient should be given reassurances as appropriate – for example, that the cause of the signs/symptoms has been identified (assuming this to be the case) and that the remedial action recommended should solve the problem. An explanation should be given to the patient as to why changes are being made – for example, that lenses are being changed because the patient has become more myopic through natural progression. The patient should be invited to ask any questions. Potential or actual aspects of non-compliance detected during the examination can be raised with the patient, and good practice reinforced. The essence of this discussion should be noted in the medical record (Veys et al., 2001). Finally, patients should be instructed of the date and time of their next aftercare appointment, and they should be advised to wear their lenses to the next aftercare visit and to bring their lens case, solutions and any other paraphernalia associated with lens wear.

Grading Scales

As an aid to accurate record keeping, health-care practitioners of all disciplines often resort to the use of standardized grading scales of various conditions. Presented in Appendix K are the Efron grading scales for contact lens complications (Efron, 2000); these provide a simple, convenient and accurate means by which clinicians can record and communicate the severity of complications of contact lens wear. The Efron grading scales were painted by an ophthalmic artist; the advantage of using painted (versus photographic) grading scales is that greater clarity can be achieved because the precise level of severity can be depicted, all other factors can be kept constant, potentially confounding artefacts can be avoided and artistic licence can be adopted. Practitioner surveys have revealed that painted grading scales are preferred to photographic scales (Efron et al., 2011).

The grading assigned to a particular condition can serve as a reference against which any future tissue change may be assessed, and can therefore influence clinical decision making. These grading scales may act as a standard clinical reference for describing the severity of contact lens complications.

GRADING SCALE DESIGN

The primary design criteria upon which the Efron grading scales are based are simplicity, convenience and ease of use by clinicians. Sixteen sets of grading images are depicted in two panels, each comprising eight complications. These 16 grading scales cover the key anterior ocular complications of contact lens wear. Those shown on the panel beginning with 'conjunctival redness' are frequently encountered; those in the other panel are less common and thus less likely to be graded routinely. On each panel, complications are depicted in the approximate order that they would be encountered in the course of a typical slit-lamp examination of the eye. Each complication is illustrated in five stages of increasing severity, from 0 to 4, with 'traffic light' colour banding from green (normal) to red (severe). The severity of the complications is based on an appraisal of accumulated evidence in the literature and clinical experience.

TABLE 39.2 Magnification of Complications shown in the Efron Grading Scales

Complication	Magnification*	Image
Corneal staining	1×	A
Corneal ulcer	1×	B
Corneal infiltrates	1×	C
Corneal neovascularization	1×	D
Papillary conjunctivitis	1×	E
Meibomian gland dysfunction	1×	F
Blepharitis	1×	G
Superior limbic keratoconjunctivitis	2×	H
Limbal redness	2×	I
Conjunctival staining	2×	J
Conjunctival redness	2×	K
Corneal distortion	2×	L
Corneal oedema	40×	M
Epithelial microcysts	100×	N
Endothelial blebs	200×	O
Endothelial polymegethism	600×	P

*Relative to a whole cornea being ×1.

IMAGE SIZE

Each complication has been painted to an equivalent level of magnification that addresses the compromise between being high enough to depict the key features of the tissue changes, and being low enough to relate to what practitioners can observe with available clinical techniques. The approximate magnification of each complication (relative to a whole cornea depicted as 1×) is given in Table 39.2. Fig. 39.17 shows the 16 complications at grade 4 severity (each of which is identified by a letter code in Table 39.2) and indicates the approximate magnification of the images with a series of size boxes.

A consequence of these magnification levels is that, although epithelial microcysts and endothelial blebs can be detected and graded at 40× magnification on a slit-lamp biomicroscope, they will not be viewed at the resolution depicted. Furthermore, endothelial polymegethism can be assessed only with the aid of an endothelial microscope. All other complications can be viewed at the resolution depicted and are capable of being graded by direct observation and/or using a slit-lamp biomicroscope at up to 40× magnification.

HOW TO GRADE

Grading is a simple procedure that can be undertaken with little additional chair time (Efron and McCubbin, 2007). The tissue change of interest should be observed directly or with the aid of a slit-lamp biomicroscope, under low and/or high magnification as required, and the grade of severity should be estimated to the nearest 0.1 scale unit. For example, a tissue change that is judged to be considerably more severe than grade 2, but not quite as severe as grade 3, may be assigned a grade of 2.8 or 2.9. Although this procedure can sometimes be difficult (Efron and Chaudry, 2007), grading to the nearest 0.1 scale unit (rather than simply assigning a whole-digit grade of 0, 1, 2, 3 or 4) affords much greater precision and increases the sensitivity of the grading scale for detecting real changes or differences in severity. Objective, automated grading is also possible using digital image capture and analysis (Peterson and Wolffsohn, 2009).

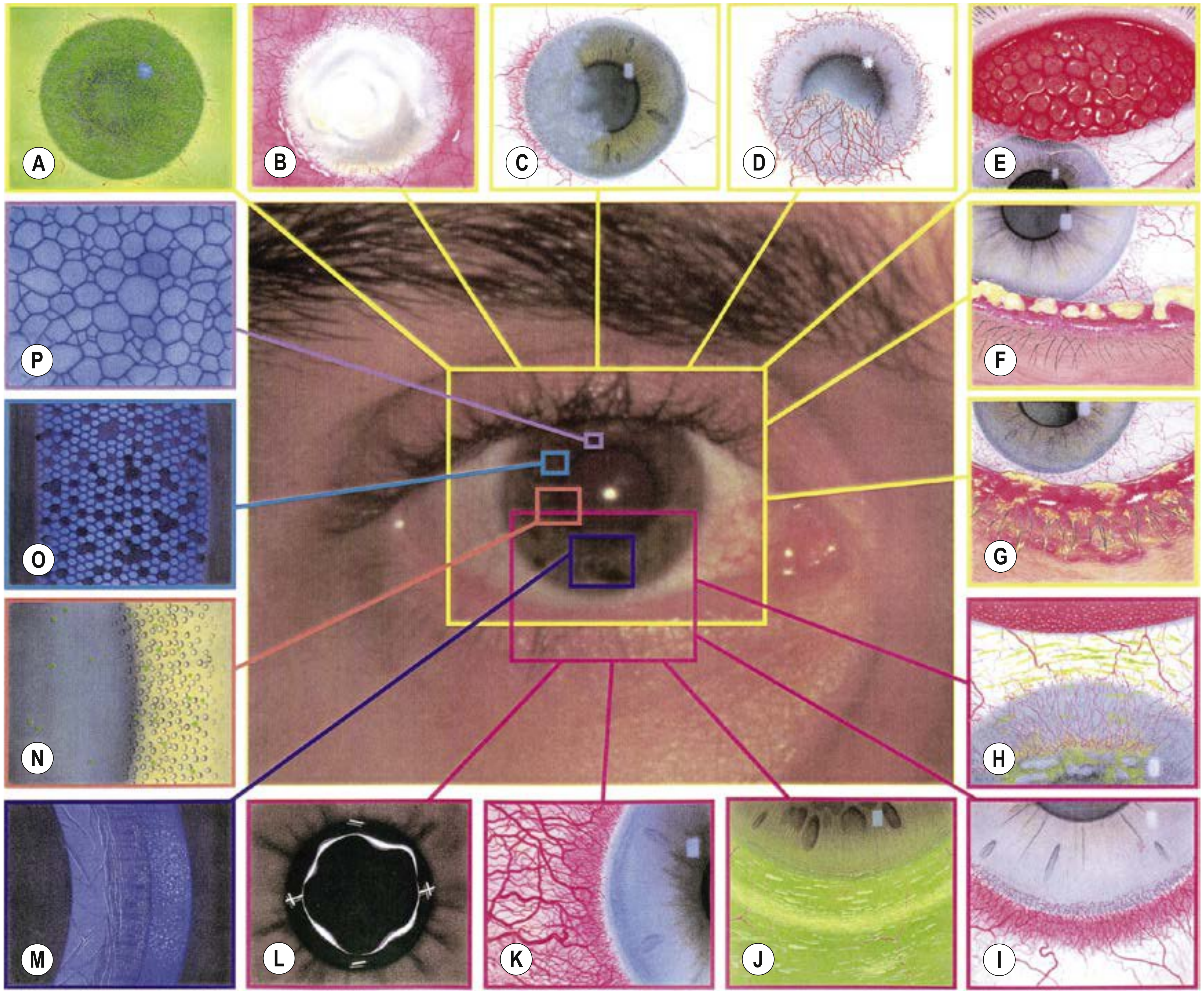


Fig. 39.17 The 16 complications represented in the Efron grading scales (presented in full in Appendix K), depicted here at grade 4 severity. The approximate magnification of each complication (relative to the whole cornea being 1× magnification) is indicated by coloured boxes interposed over the image of the eye. The 16 complications are labelled with a letter code and are identified in Table 39.2.

HOW TO RECORD GRADING

Various grading scales are available, so it is important to designate clearly the grading system used and the specific tissue change being graded. A more expedient approach would be to record the 16 tissue changes in a computerized or paper medical record, each with an accompanying box, for entering the assigned grade. It may be necessary to make additional annotations to describe the condition more fully – for example, to indicate the location of the pathology. Specially designed electronic medical records could include either the picture-based grading scales or computer morphs of the images. The latter have been shown to offer considerable utility in terms of recording gradings (Efron et al., 2002).

INTERPRETATION OF GRADING

The five-stage 0–4 grading scale is based on a universally accepted concept whereby a higher numeric grade denotes greater clinical severity. This schema can be applied to any tissue change. The designation and general interpretation of each grading step are shown in Table 39.3; it must be recognized that these are only very general guidelines, and are not intended to replace sound professional judgement.

There are two exceptions with respect to the above interpretation. Corneal ulceration may require urgent action when detected or even suspected at any level of severity. Endothelial blebs require no clinical action, even at grade 4.

TABLE 39.3 Designation and Interpretation of the Various Levels of Severity shown in the Efron Grading Scales

Grade	Severity	Colour Band	Clinical Interpretation
0	Normal	Green	Clinical action not required
1	Trace	Lime	Clinical action rarely required
2	Mild	Yellow	Clinical action possibly required
3	Moderate	Orange	Clinical action usually required
4	Severe	Red	Clinical action certainly required

When using grading scales for the first time, a confidence range of about 1.2 is to be expected (Efron et al., 2001); however, with experience, this confidence range may reduce to 0.7 grading scale units. In general, a change or difference of more than about 1.0 grading scale unit, or a level of severity of more than grade 2, is considered to be clinically significant. Practitioners can determine their own grading precision using a grading tutor (Efron and Morgan, 2001).

DETERMINANTS OF GRADING PERFORMANCE

Reliable and accurate grading of contact lens complications is thought to be a function of three attributes, which collectively constitute the 'clinical skills set' (Efron et al., 2003a):

1. knowledge – the broad knowledge base that underpins the clinical task, e.g. that attribute gained after optometric training
2. training – the pedagogic experience of teaching and guided learning, e.g. gained through lectures, tutorials, workshops and directed learning
3. experience – the repeated use of a grading scale over time, e.g. that attribute gained with unguided learning by 'trial and error'.

Efron et al. (2003a) found that those without ophthalmic training (engineering students) were able to grade as accurately as optometrists, although less reliably and with less confidence. They concluded that the possession of a relevant clinical skills set ensures that one is more reliable and confident when grading contact lens complications. Further studies revealed that grading reliability is not enhanced by training, but does improve with experience (Efron et al., 2003b).

General Approaches to Solving Problems

Patient-reported symptoms generally fall into three broad categories, relating to the following:

1. appearance of the eyes – for example, 'my eyes have been quite red lately'
2. ocular discomfort – for example, 'the lenses are irritating my eyes'
3. poor visual quality – for example, 'everything seems a little blurry'.

Indeed, it was probably the realization that this is the classical pattern of symptomatology in contact lens practice that led to the adoption of the catchphrase advice that is often related to patients – to check periodically that one's eyes 'look good, feel good and see good (well)' (see Chapter 38). It is pertinent, therefore, to consider strategies for solving problems relating to these categories of symptoms.

EYE REDNESS

Conjunctival and/or limbal redness is so obvious and easily recognizable that it is perhaps the only sign of contact lens wear that is also reported as a symptom by patients. Indeed, excessive eye redness is cosmetically unsightly and is generally perceived as a potential disadvantage of wearing contact lenses. It is recognized in eye care generally that the clinical presentation of a 'red eye' can be one of the most difficult cases to solve owing to the numerous possible causes that are known. This problem may be even more complex in a contact lens wearer because there are many additional contact-lens-related causes of red eye.

Characterizing Eye Redness

Throughout the literature, the terms hyperaemia, injection, vascularity and redness are used synonymously. These terms are defined as follows:

- hyperaemia – increased blood in a part, resulting in distension of the blood vessels (Osol, 1973)
- injection – a state of hyperaemia (Osol, 1973)
- vascularity – the quality of vessels (Osol, 1973)
- redness – of or approaching the colour seen at the least-refracted end of the spectrum, of shades varying from crimson to bright brown and orange (Sykes, 1976).

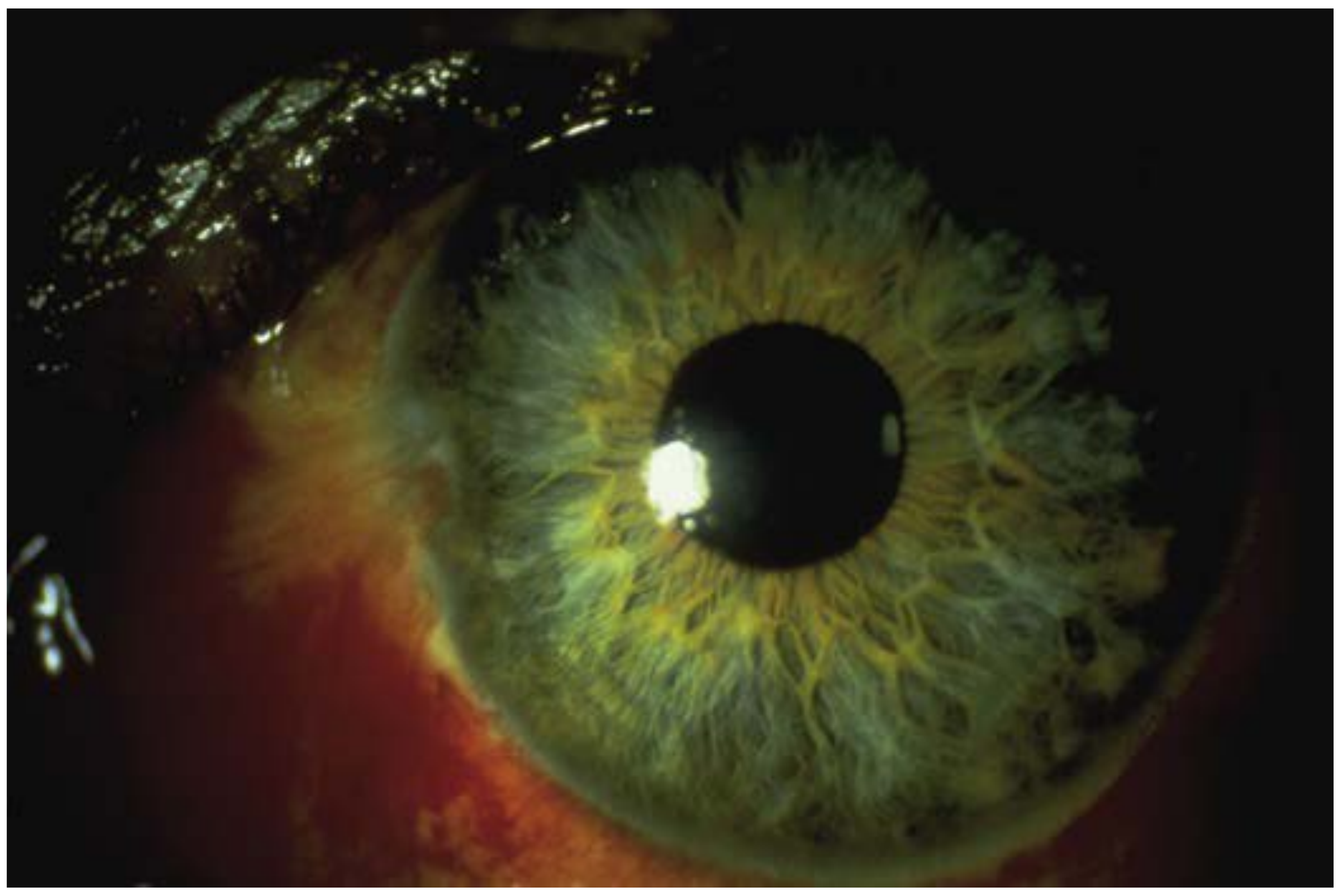


Fig. 39.18 Conjunctival haemorrhage in the eye of a soft lens wearer who was struck in the eye by a squash ball. Note the clear avascular zone around the limbus.

In strict terms, 'hyperaemia' or 'injection' is the cause and 'redness' is the effect. That is, an increased volume of blood in the conjunctival vessels (hyperaemia or injection) causes an increased appearance of redness. The term 'vascularity' is somewhat ambiguous and could represent both the cause and effect.

Strategies for Diagnosing and Solving Eye Redness

When a contact-lens-wearing patient presents with a red eye as a primary complaint, the initial diagnostic step is to determine whether or not the problem is related to lens wear. This can often be simply solved by removing the lens; eye redness should dissipate quickly if the problem is purely lens related. If, following lens removal, the redness has not dissipated by the end of the office visit – and all other possible causes of redness have been ruled out – the patient should be given instructions to monitor for dissipation of redness and to report back if it remains red after a few hours. The possibility that the lens was somehow exacerbating a complication unrelated to lens wear itself should not be discounted.

Another differential diagnosis that may be necessary when presented with an extremely red eye is to determine to what extent the redness is due to conjunctival injection or ciliary flush. Two simple tests can be applied. A sterile cotton bud can be held lightly against the bulbar conjunctiva in the region of redness and gently moved from side to side. The conjunctival vessels will move but the ciliary vessels will remain in a fixed position. It can then be determined whether the redness relates primarily to the 'moving' vessels (indicating conjunctival involvement) or the 'static' vessels (indicating ciliary involvement).

An alternative test is to instil a decongestant into the eye (Jose et al., 1984). The effect of a decongestant is limited to the superficial conjunctival vessels; these drugs have no effect on the deeper ciliary vessels. Thus, if the instillation of a decongestant alleviates eye redness, the condition is primarily conjunctival. If the decongestant has no impact on the appearance of the eye, then the redness can be attributed to excessive ciliary flush.

A subconjunctival haemorrhage can be easily differentiated from conjunctival and/or ciliary hyperaemia because of the stark appearance of an intensely 'blood-red' eye and the lack of hyperaemia around the limbus (Fig. 39.18).

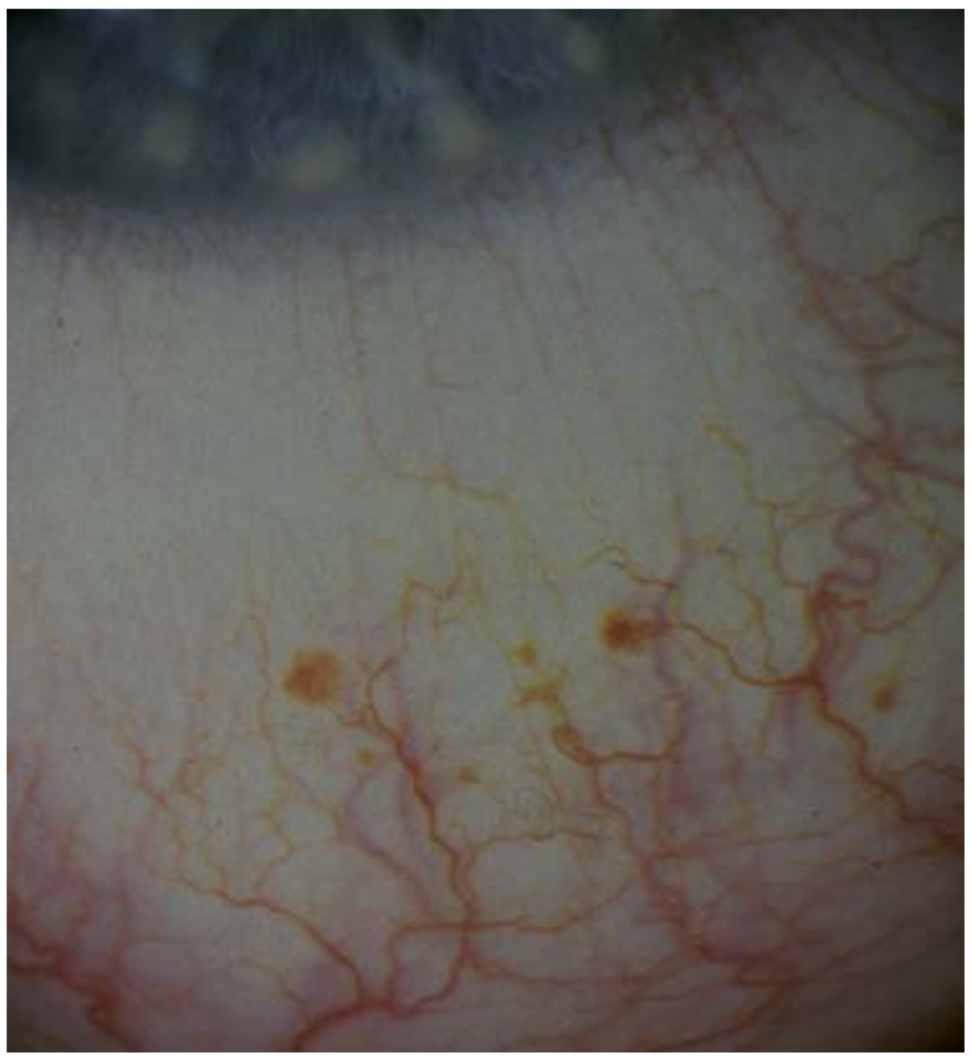


Fig. 39.19 Small conjunctival haemorrhages observed in a patient wearing soft lenses. (Courtesy of Hilmar Bussaker, Bausch & Lomb Slide Library.)

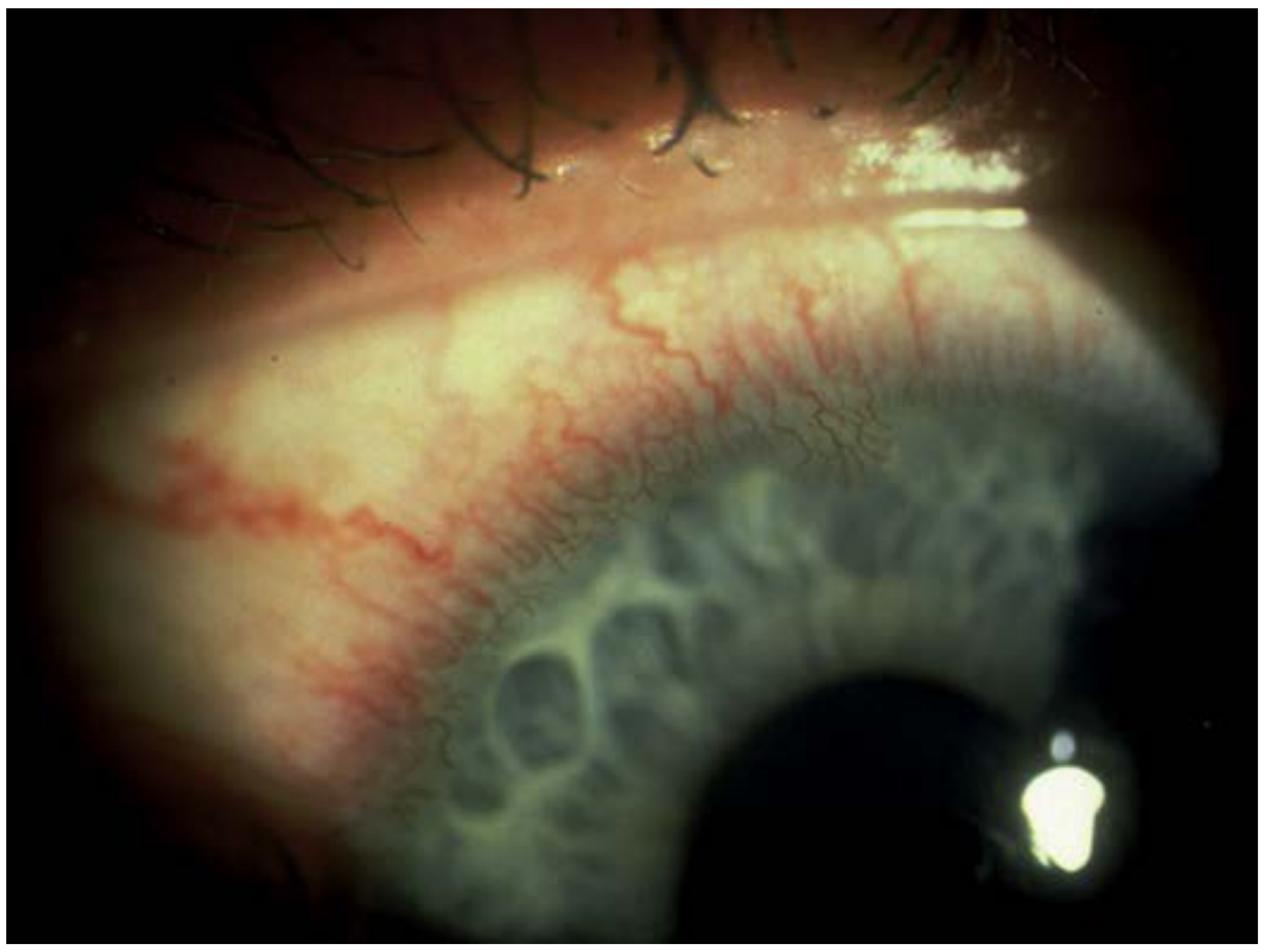


Fig. 39.20 Limbal redness suggestive of corneal pathology.

Small haemorrhages of individual conjunctival vessels can also increase conjunctival redness (Fig. 39.19), but again these are self-evident and differential diagnosis from vascular engorgement is clear.

Assuming that a given case of eye redness is lens related, it is necessary to determine whether the source of the problem is the cornea or the conjunctiva. Conjunctival redness associated with a quiet limbus and absence of pain indicates a primary conjunctival problem. Conjunctival redness associated with an injected limbus and severe pain indicates corneal involvement, or indeed a problem that is related exclusively to the cornea (Fig. 39.20).

Redness of both the limbus and bulbar conjunctiva may indicate a coexistence of corneal and conjunctival pathology (Fig. 39.21).

Careful examination of the anterior ocular structures with a slit-lamp biomicroscope, and inspection of the lens at high magnification, will generally reveal the cause of the problem. It may also be necessary to prescribe different care systems and differentially diagnose the effects of various solutions over time.

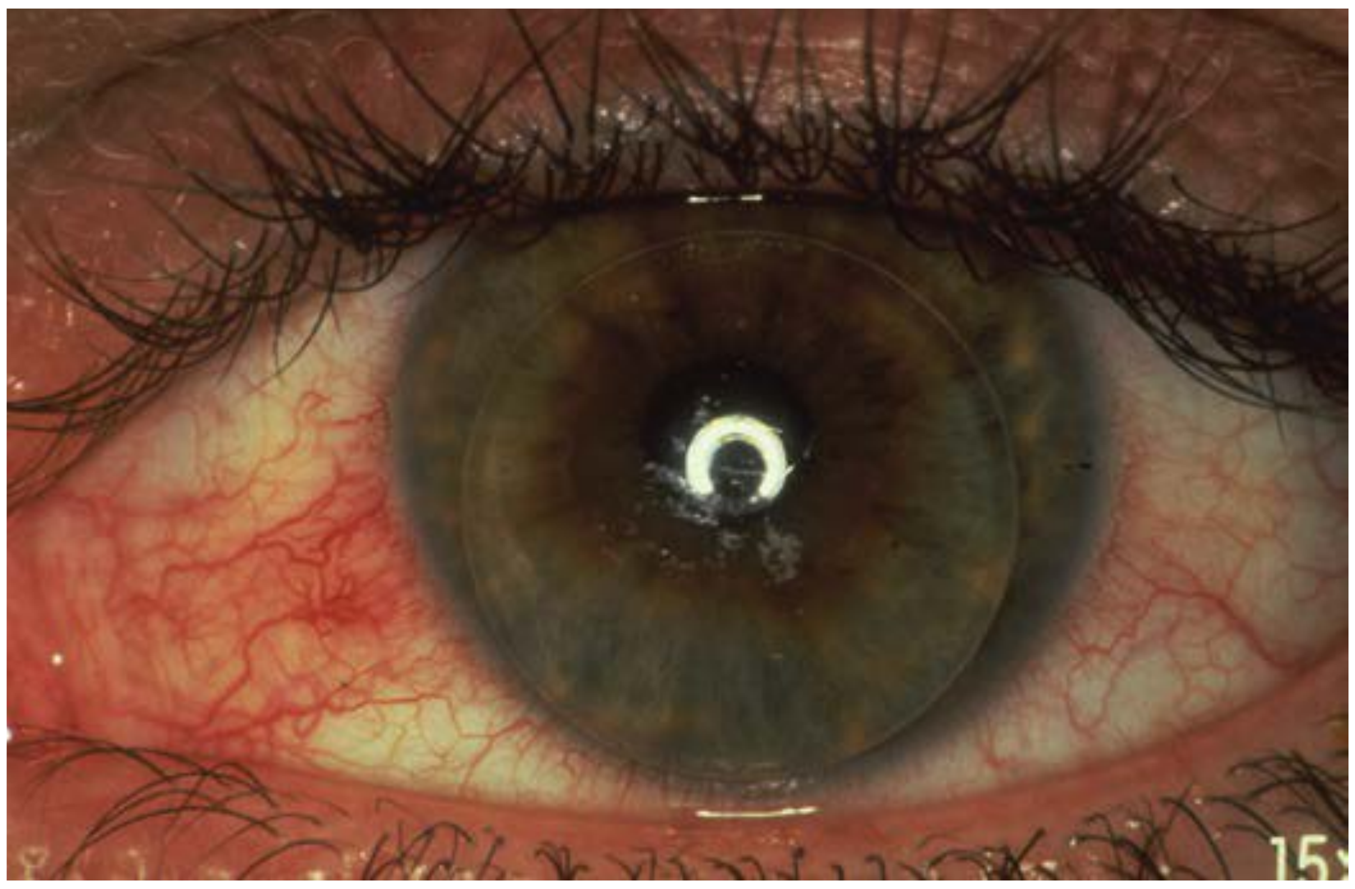


Fig. 39.21 Combination of limbal and bulbar conjunctival redness in a rigid lens wearer, possibly due to 3 and 9 o'clock staining (i.e. corneal involvement) and conjunctival desiccation (i.e. conjunctival involvement).

If the red eye is deemed to be unrelated to lens wear, then other possible causes must be investigated. This may involve a full ocular examination involving the use of direct and indirect ophthalmoscopy and tonometry.

DISCOMFORT

The most common patient symptom that will confront a contact lens practitioner is that of discomfort, and in particular, 'dryness' (Brennan and Efron, 1989; Begley et al., 2000). Reconciliation of patient symptoms with clinical signs is a constant challenge to all health-care practitioners (Nichols et al., 2013). There is always the potential to devote undue attention to a complaint that bears little significance to the well-being of the patient, or conversely to give token consideration to a symptom arising from a potentially serious condition. Furthermore, there are many signs that the clinician detects that also have a major influence upon patient management but for which the patient shows no or minimal symptoms. Conditions that may be asymptomatic, such as corneal neovascularization, microcystic oedema and endothelial polymegethism, are important pathophysiological signs that require some form of treatment – however, the most rewarding management plans, from the perspective of the patient, are those that alleviate discomfort.

During adaptation to contact lens wear, soft lenses offer a greater level of comfort than do rigid lenses. Indeed, a study that assessed comfort of hydrogel lenses over short wearing periods found that more than half of lens wearers were unaware of the presence of the lens in their eyes at any given moment (Efron et al., 1986). Both soft and rigid lenses are very comfortable once the patient has adapted to the lenses. Nonetheless, occasions will arise when lenses become less comfortable. Because of the subjective nature of discomfort symptoms, most reports in the literature concerning this topic have been anecdotal. Here, a systematic approach for quantification of discomfort is outlined, and management strategies for solving this problem are advanced.

The neural mechanisms by which the conjunctiva and cornea produce ocular sensibilities during contact lens wear have yet to be elucidated. Certainly, these mechanisms are somewhat imprecise. For example, ocular sensibilities are often poorly differentiated such that the description and localization of an abnormal event in the eye by a patient are often inaccurate. It is therefore not surprising that patient reports of ocular sensations can be confusing to

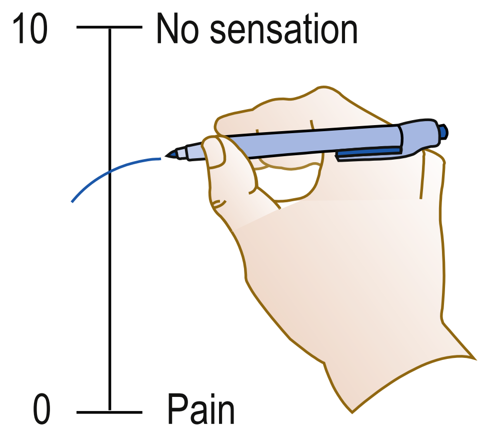


Fig. 39.22 Vertical analogue scale used to quantify subjective comfort, whereby a higher number indicates greater comfort.

the practitioner. In the absence of major anomalies of the lens or eye, the comfort of the lens appears to depend upon the interaction between the lid – especially the lid wiper – and lens.

The exact nature of the stimulus that gives rise to the sensation of dryness is also unclear and the reasons for the high frequency of this symptom in contact lens wearers are a matter for speculation, given that it is the least frequently reported symptom of non-lens wearers (McMonnies and Ho, 1986). As there are no specific 'dryness receptors' in human tissue, the ocular sensation of 'dryness' must be a response to specific coding of afferent neural inputs. One may hypothesize that 'dryness' results from an interference with tear physiology and structure by the contact lens – the specific mechanism being an increased tear evaporation and faster break-up of the tear film. The sensation may also arise from the neural misinterpretation of stimuli seemingly unrelated to dryness, such as direct mechanical interaction of the lens with the ocular tissues, lens dehydration or vasodilation and the subsequent rise in local temperature (Efron and Brennan, 1996).

Characterizing Symptoms of Discomfort

Patients can employ one or more of a myriad of descriptions to describe symptoms of discomfort during contact lens wear. Terms that may be used include:

- scratchy
- dry
- watery
- itchy
- gritty
- hot
- cold
- burning
- tired
- irritated
- uncomfortable
- sore
- hurting
- aching
- painful.

A systematic approach can be applied for quantifying the level of subjective discomfort experienced during lens wear. Specifically, the severity of discomfort can be described in three ways:

1. Nominal – purely descriptive terms are used, such as mild or severe.
2. Ordinal – the level of severity is ranked on a scale of discrete steps, e.g. grades 0, 1, 2, 3 or 4. Descriptors may be employed for the extreme grades as a guide, e.g. grade 0 means 'no sensation' and grade 4 means 'extreme pain'.
3. Analogue – where the level of comfort is indicated on a continuous scale. A popular technique employed in contact lens research is the vertical analogue comfort scale (Fig. 39.22). The patient is invited to mark the position on a vertical scale corresponding to the level of comfort. (The reason why the scale is oriented vertically is to avoid potential bias that may invalidate the use of a horizontal scale, as a result of 'handedness'.) The distance along the scale from the zero position is measured and taken as an index of the degree of comfort (so the higher the score, the more comfortable is the lens).

Strategies for Solving Symptoms Relating to Discomfort

The following strategies can be employed to determine whether the discomfort is eye or lens related:

- Always be on the lookout for concurrent ocular pathology that may be unrelated to lens wear (e.g. glaucoma).
- Consider the laterality of the discomfort – for example, discomfort caused by a toxic reaction to a contact lens solution would be expected to be bilateral, whereas discomfort caused by damaged contact lens would be expected to be unilateral.
- Remove the lenses – persistent discomfort following lens removal suggests an ocular problem, whereas relief of discomfort following lens removal suggests a lens problem.
- Swap the lenses between the eyes – an ocular problem is indicated if unilateral discomfort remains in the same eye after the lenses have been swapped; a lens-related problem is indicated if unilateral discomfort transfers to the other eye after the lenses have been swapped.
- Prescribe ocular lubricants – relief after an ocular lubricant has been instilled into the sore eye suggests a mechanical or abrasive source of the discomfort.

There are many possible causes of lens-related discomfort. These causes, and strategies for alleviating the problem, include:

- Poor-fitting lenses – change to a better-fitting lens; specifically, a lens of larger diameter and / or steeper base curve may move less and therefore be more comfortable.
- Physical defects in lenses – replace the lens and / or change to a superior product.
- Particulate matter partially embedded in lenses – replace the lens.
- Foreign bodies beneath lenses – rinse the lens.
- End-of-day dryness in hydrogel lens wear – use a silicone hydrogel lens to enable longer wearing times (Dumbleton et al., 2008).
- A toric soft lens might be slightly less comfortable than its spherical equivalent because of thick stabilization zones – employ a toric design with a thinner profile.
- Dehydration of hyperthin hydrogel lenses can lead to epithelial drying and discomfort (Fig. 39.23) – refit the patient with a thicker lens.
- Older lenses tend to feel drier – replace lenses more frequently.
- Lenses with surface deposits can be uncomfortable – replace the lens and increase the replacement frequency.

If a patient complains of lens discomfort, and there is no apparent cause after having carefully examined the lens and eye, the lens should be replaced.

Various forms of contact-lens-related ocular pathology can cause discomfort; it should be noted that the apparent severity of the tissue pathology does not necessarily correlate with the degree of discomfort suffered by the patient. Such conditions include the following:

- Corneal epithelial microcysts – may cause slight discomfort.
- Corneal stromal oedema – moderate oedema (5% swelling) can cause mild discomfort but severe oedema (20% swelling) can be very painful, although the pain may be attributed to associated pathology such as an anterior uveal reaction. Oedema associated with the corneal exhaustion syndrome may be very uncomfortable.

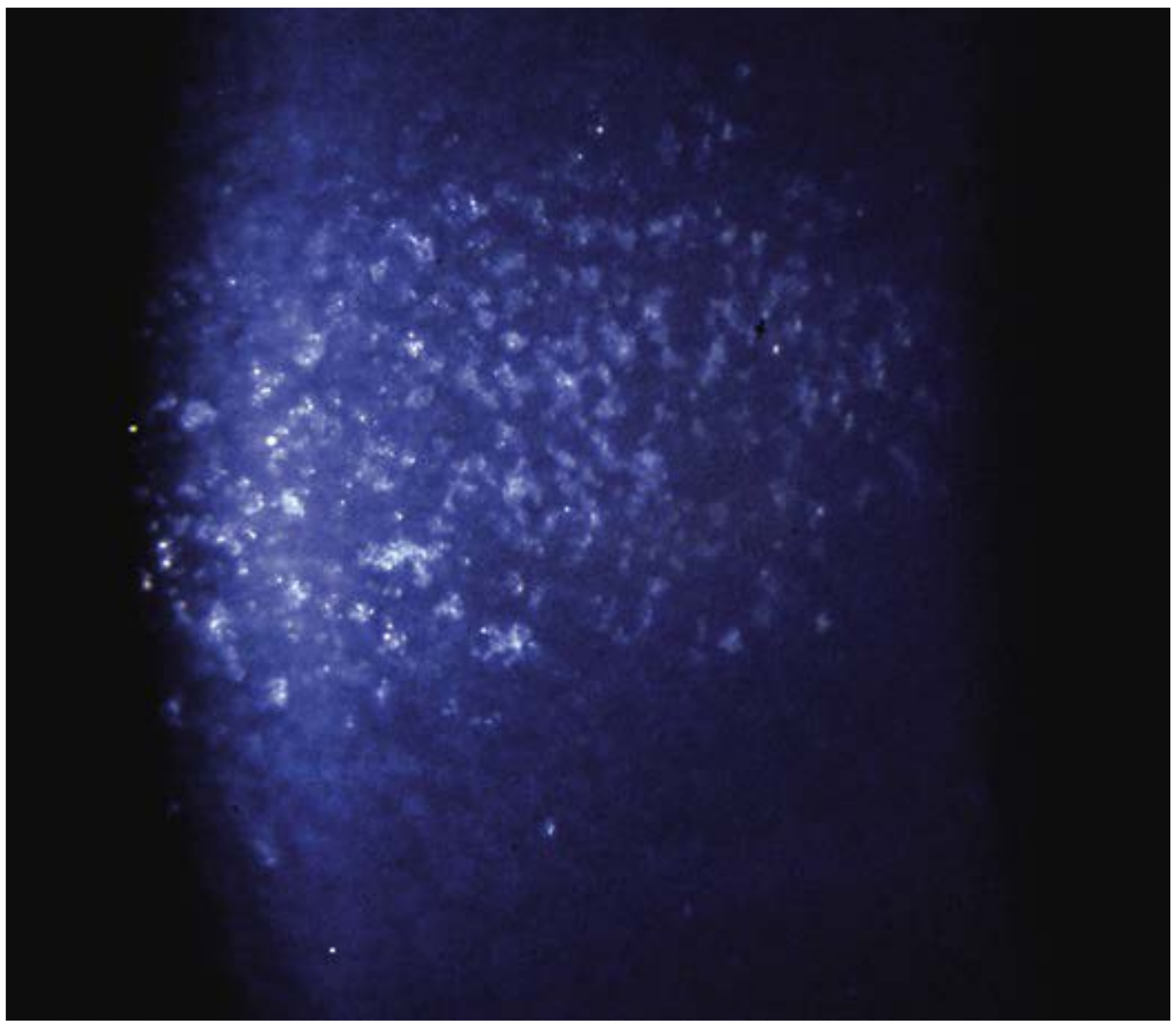


Fig. 39.23 Epithelial desiccation caused by a hyperthin experimental soft lens. (Courtesy of Brien Holden, Bausch & Lomb Slide Library.)

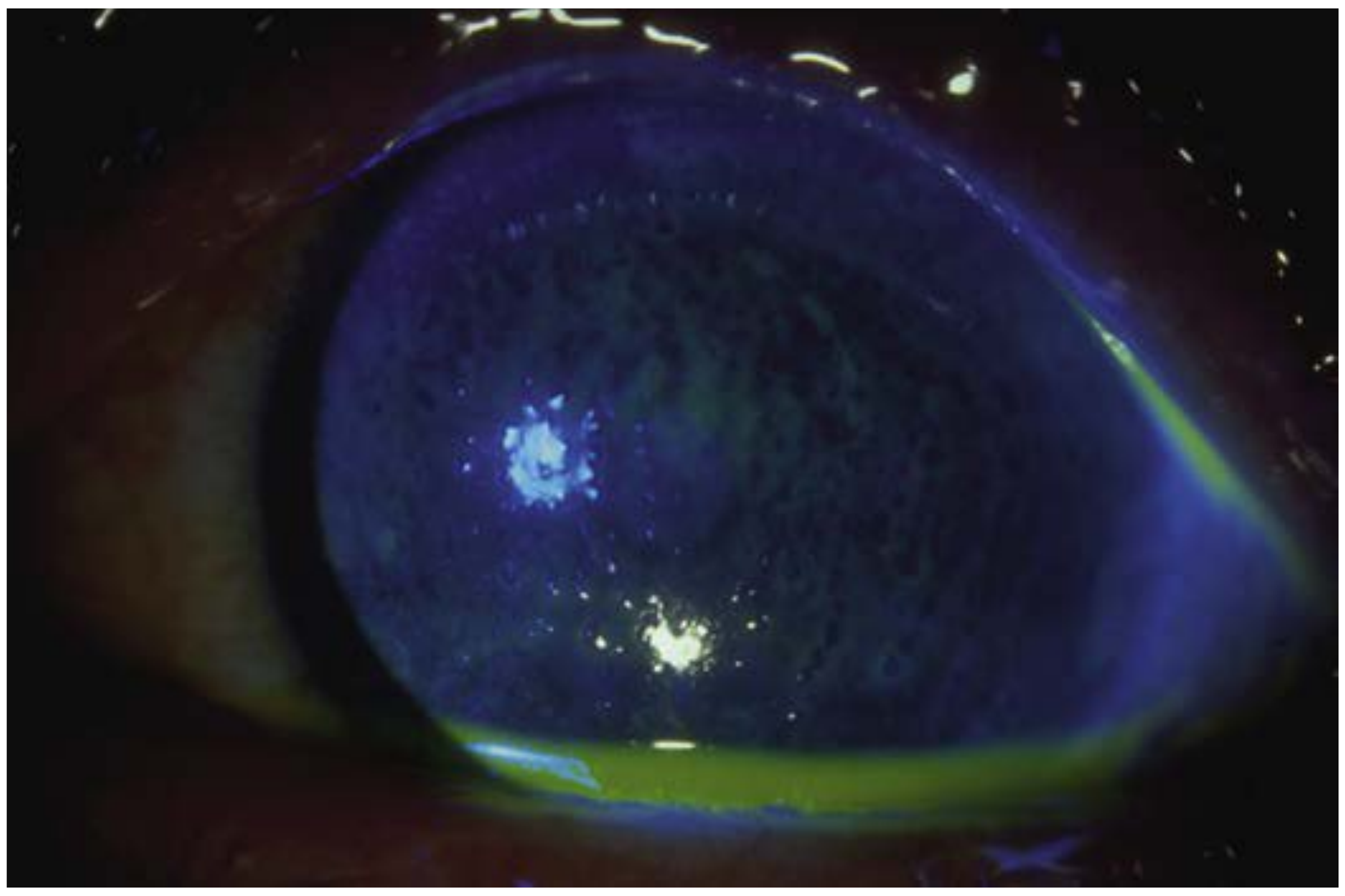


Fig. 39.24 Severe toxicity reaction due to the patient inadvertently introducing a soft lens cleaning solution directly into the eye (having mistaken this for a wetting solution). Severe corneal staining is revealed with fluorescein. (Courtesy of W. Vreugdenhil, Bausch & Lomb Image Library.)

- Contact-lens-associated acute red eye (CLARE) – occurs in extended-wear patients, and can be very painful; lens removal often gives immediate relief.
- Superior limbic keratoconjunctivitis – causes increased lens awareness and itching; symptoms are alleviated by ceasing lens wear.
- Infectious keratitis – can be extremely painful, especially Acanthamoeba keratitis, where patients can be suicidal.
- Tear film dysfunction – discomfort is due to lens surface drying (Versura et al., 2000); ocular lubricants can provide short-term relief.

Ocular discomfort during contact lens wear may be due to the use of associated lens care products. Specifically, the discomfort may be related to:

- solution pH and tonicity
- solution toxicity (Fig. 39.24)

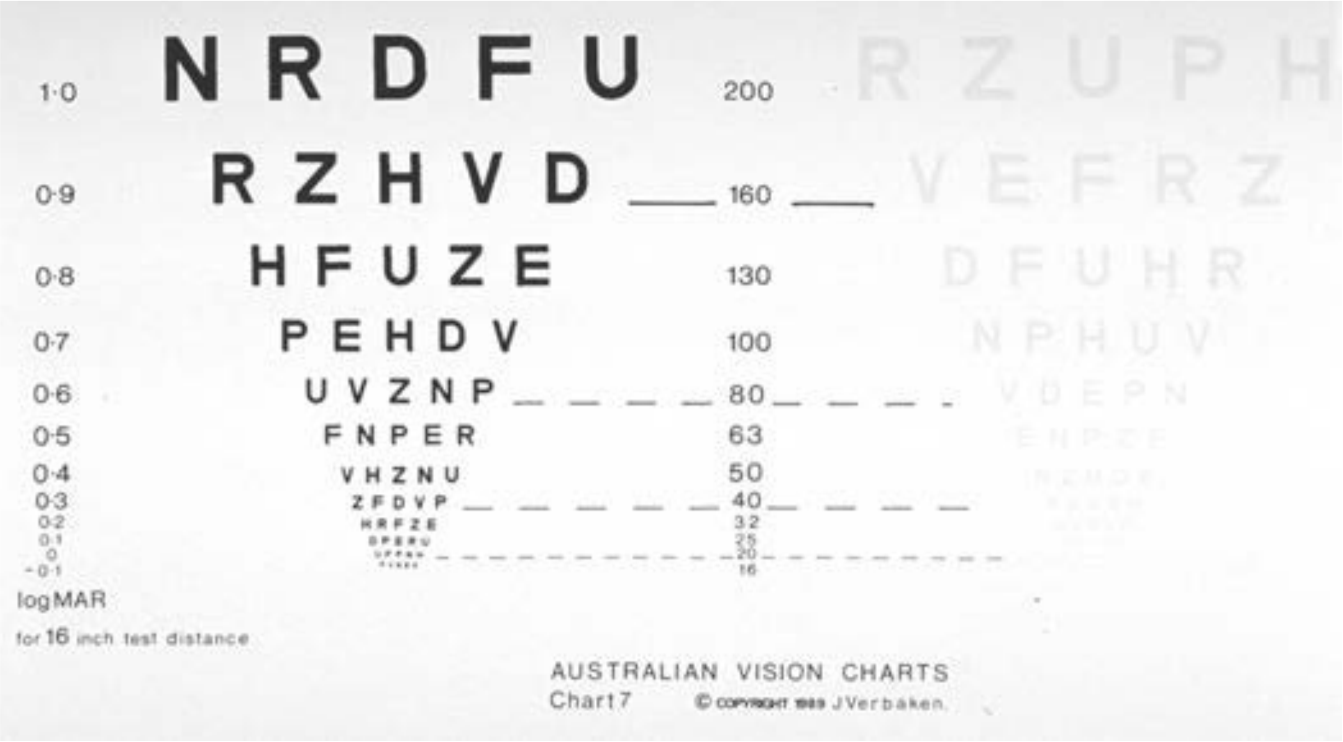

1·0 N R D F U 200 R Z U P H
0·9 R Z H V D 160 V E F R Z
0·8 H F U Z E 130 D F U H R
0·7 P E H D V 100 N P H U V
0·6 U V Z N P 80 V D E P N
0·5 F N P E R 63
0·4 V H Z N U 50
0·3 Z F D V P 40
0·2 32
0·1 25
0 20
-0·1 16
logMAR
for 16 inch test distance
AUSTRALIAN VISION CHARTS
Chart 7
© copyright J Verbaken

Fig. 39.25 High-contrast (letters on the left) and low-contrast (letters on the right) logMAR visual acuity chart.

- solution allergy
- solution-induced corneal staining
- residual unneutralized hydrogen peroxide
- hydrogen peroxide burn.

POOR VISION

The causes of vision loss during contact lens wear are not always obvious, and a definitive diagnosis may be difficult owing to the transient or inconsistent nature of the problem (Brennan and Efron, 1996). A wide variety of factors may lead to vision problems during contact lens wear; in this section, consideration will be given to ways in which vision loss can be denoted, and suggestions will be offered for strategies to determine the cause of suboptimal vision during contact lens wear.

Characterizing Symptoms of Poor Vision

In addition to measuring vision with and without contact lenses, additional descriptive information relating to symptoms of poor vision should be obtained from the patient, such as:

- severity – mild or severe
- consistency – constant or fluctuating
- onset – immediate or delayed
- proximity – difficulty at distance or near
- persistence – whether the problem persists throughout the period of lens wear and / or following lens removal
- description – whether the problem is best described as blur, haze, glare or some other descriptor.

Other techniques for assessing vision may help characterize the problem. These include the following:

- Contrast sensitivity function – this may be suppressed during adaptation, but otherwise should be no different from that obtained with the best corrected spectacle prescription.
- High- and low-contrast acuity charts (Fig. 39.25) – reduced acuity with a high-contrast chart suggests a refractive problem, whereas reduced acuity with a low-contrast chart indicates a 'non-refractive' problem, such as poor lens fit, ocular pathology or excess lens deposition.
- Glare sensitivity test – a bright light is positioned next to a low-contrast eye chart facing the patient; reduced vision under this condition indicates glare sensitivity,

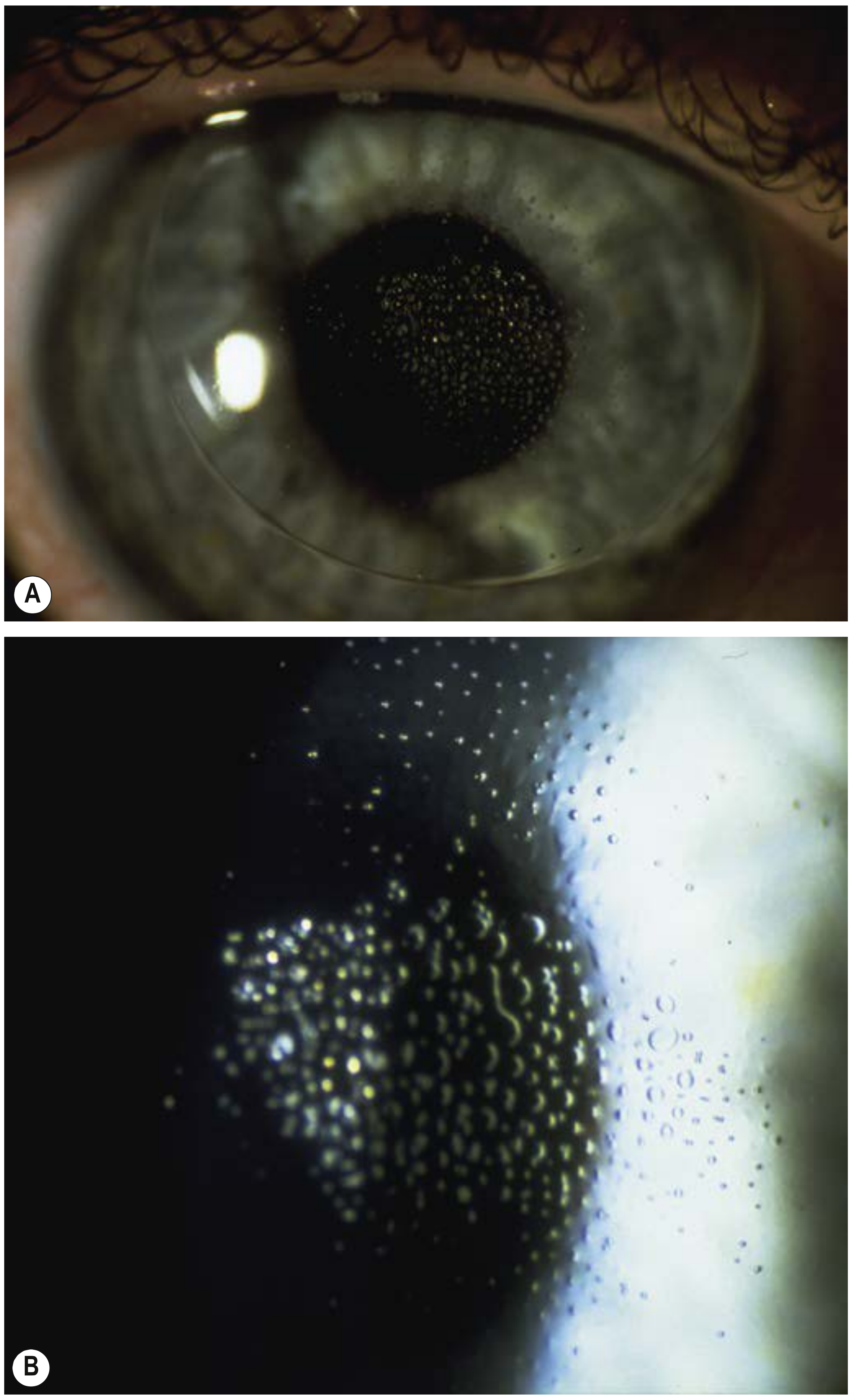


Fig. 39.26 An unusual case of vision loss with rigid lenses. (A) A fine stippled appearance is evident using the slit lamp with general diffuse illumination. (B) A high-magnification photograph taken through the slit-lamp eyepiece confirms a case of extensive dimple veiling, due to bubble formations beneath the lens. On questioning, it was discovered that the lens was sprayed with 'fizzy' aerosol saline prior to lens insertion. Vision recovered after a few hours. (Courtesy of Sylvie Sulaiman, Bausch & Lomb Slide Library.)

which can be due to conditions that scatter light, such as epithelial oedema, epithelial microcysts and anterior-chamber flare.

Strategies for Solving Symptoms Relating to Poor Vision

After the symptoms of poor vision with contact lenses have been fully characterized, the following general strategies can be employed to help resolve the problem:

- Restoration of vision immediately after lens removal (with a corrective trial lens before the eye) suggests a lens-related problem.
- Sustained vision loss after lens removal (with a corrective trial lens before the eye) suggests an ocular problem (which may or may not be related to lens wear) (Fig. 39.26).
- Unilateral vision loss may be due to the lens or uniocular pathology.
- Bilateral vision loss may be due to a refractive cause or to general ocular pathology (e.g. toxic or allergic solution reaction) or systemic disease (e.g. diabetes).
- Worse vision immediately after a blink may signal excessive lens movement and either a flat fit (corrected by fitting the lens more steeply) or inappropriate lens rotation in the case of a soft toric lens (corrected by employing better lens stabilization techniques). This indicator is correlated with the appearance of keratometer mires before and after the blink (discussed above; see Fig. 39.2).
- Improved vision immediately after a blink may signal a tight fit (corrected by fitting the lens more loosely).

The following causes of vision loss with contact lenses relate to spherical refractive error:

- Patients may be unaware that the lens has become displaced from the cornea onto the sclera, or even lost from the eye, leaving vision uncorrected – verify the presence or absence of the lens.
- Shifts in refractive error can reduce vision – check the refraction.
- Lens power may have been incorrectly ordered and supplied – check the record card against the power specified on the lens packaging.
- Lens power may have been ordered correctly but supplied incorrectly – check the record card against the power specified on the lens packaging.
- Lens power may be incorrect (manufacturing/packaging error) – measure the power of the lens and check this against the power specified on the lens packaging.
- The tear layer beneath a rigid lens can have significant optical power – reconcile ocular refraction, overrefraction, corneal topographic assessment, lens parameters and observed fluorescein pattern.
- Flexure of thick soft lenses can induce power shifts – fit lenses that are thinner and/or made of a material of lower modulus.

An uncorrected astigmatic component of a refraction with contact lenses can be due to:

- an astigmatic shift in refraction
- residual uncorrected astigmatism
- mislocation of toric lens cylinder axis
- lens power may have been incorrectly ordered and supplied – check the record card against the power specified on the lens packaging
- lens power may have been ordered correctly but supplied incorrectly – check the record card against the power specified on the lens packaging
- lens power may be incorrect (manufacturing/packaging error) – measure the power of the lens and check this against the power specified on the lens packaging
- corneal warpage.

Contact lens correction of presbyopia entails a variety of visual compromises, such as:

- Monovision correction – degrades stereopsis at near.
- Alternating-vision bifocal lenses – incomplete or improper lens translation will compromise vision.
- Simultaneous-vision bifocal lenses – the visual system may have difficulty in processing clear and blurred images on

the same region of retina; non-optimal pupil size will degrade vision.

Most non-optical causes of vision loss relate to problems of poor lens fitting, such as the following:

- Flat-fitting lenses will decentre away from the pupil.
- Excessive lens movement can degrade vision.
- Steep-fitting lenses may buckle in the centre and degrade vision.
- Hyperthin hydrogel lenses can dehydrate the epithelium, leading to vision loss.
- Lenses of low oxygen transmissibility can induce gross oedema, leading to vision loss.
- Poor lens surface quality – due to manufacturing problems, lens deposits or excessive surface drying – can degrade vision (Tutt et al., 2000).

A variety of pathological and non-pathological ocular problems relating to lens wear can cause vision loss, including:

- corneal infection
- tear film dysfunction
- corneal epithelial desiccation
- corneal epithelial oedema
- corneal stromal oedema
- corneal stromal infiltrates
- corneal neovascularization
- corneal warpage
- binocular vision problems.

Conclusion

Aftercare examinations should be undertaken routinely on all contact lens wearers, on the basis that 'prevention is better than cure'. A thoughtful approach to these visits should, in most cases, result in the early detection of subclinical problems. Remedial action can often be undertaken without the patient being aware that a problem exists.

Patients can present for unscheduled visits complaining of one or more of a large number of possible problems – for reasons that are not necessarily the fault of the patient or practitioner. A strategic approach can be adopted, whereby patient-reported problems are considered in the context of three broad categories – eye appearance (redness), discomfort and poor vision. This approach should facilitate an efficient determination of a likely cause and appropriate remedial action can be put into effect. The outcome would hopefully be a happy patient who is motivated to continue to derive the undoubted benefits of contact lenses.

Access the complete references list online at http://www.expertconsult.com.

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40

Complications

NATHAN EFRON

Introduction

Just as contact lenses have become easier to fit over the past century, our knowledge base of the ocular response to lens wear has expanded exponentially over the same period. Thus, there has been a commensurate shift in emphasis in contact lens practice away from the technical skills of lens fitting (although these are certainly still required) and more towards the theoretical knowledge and clinical diagnostic skills required for aftercare management and problem solving.

Contact lenses can adversely affect most of the anterior ocular structures, and the conditions described in this chapter are categorized in terms of these anatomical structures. This schema reflects the natural approach to clinical decision making, whereby the initial observation and consideration of a problem begin with an examination of the affected ocular tissue.

This chapter reviews the key ocular responses to contact lens wear, some of which can have serious consequences (e.g. microbial keratitis), and some of which are benign (e.g. endothelial blebs). Each of these conditions can present at various levels of severity so, to assist the reader in gaining an appreciation of this, attention is drawn to the Efron grading scales for contact lens complications in Appendix K. Throughout this chapter, references will be made to various grades of severity referenced against a five-point scale that extends from 0 (normal) to 4 (severe). More details on the application of the use of grading scales in practice are given in Chapter 39.

Eyelids

The eyelids can impact upon, and be affected by, a contact-lens-wearing eye by way of their pattern of movement (e.g. blinking), their physical state (e.g. ptosis), their general state of health and the condition of the eyelashes. Each of these factors will be considered in turn.

BLINKING

Contact lenses elicit reflex blinking during lens insertion, removal and other instances of manual manipulation. Also, as a result of a reflex blink, contact lenses may mislocate or become dislodged from the eye. Both soft and rigid lens wear cause the spontaneous blink rate to increase (Carney and Hill, 1984; Hill and Carney, 1984). In rigid lens wear, this change may be more related to reflex blinking rather than spontaneous blinking; that is, the increased blink rate may be a result of continual irritation caused by the lens edge buffeting against the lid margin. Such alterations to blink rate are not thought to be permanent.

Contact lenses can affect the pattern of blinking. A decrease in the frequency of occurrence of long-duration interblink periods occurs in association with rigid lens wear, but not soft lens wear. Neither rigid nor soft lens wear alters the proportion of complete, incomplete, twitch and forced blinks. Infrequent or incomplete blinking with contact lenses (Fig. 40.1) can cause a number of problems, including lens surface drying and deposition, epithelial desiccation, post-lens tear stagnation, hypoxia and hypercapnia, and 3 and 9 o'clock staining. Faults in lens design and fitting can interfere with proper blink-mediated lid–lens interaction. Fewer complete eyeblinks, more incomplete eyeblinks and more eye-blink attempts were observed in rigid lens wearers with 3- and 9-o'clock staining compared with those with minimal staining and non-wearers (van der Worp et al., 2008).

There are essentially two options when faced with a clinical problem relating to non-pathological disorders of spontaneous blinking activity associated with contact lens wear, such as infrequent and / or infrequent blinking. These options are to train patients to modify their blinking activity (Collins et al., 1987), and / or to alter the lens type or lens fit.

Practitioners should always be alert to the possibility that apparent anomalies in the type or pattern or blinking activity in a contact lens wearer may be attributable to unrelated disease states. Interruptions to the neural input and / or muscular systems of the eyelids can adversely affect normal spontaneous blinking activity. For example, patients with Parkinson's disease exhibit a low blink rate. Increased mechanical resistance to eyelid movement, as in Graves' disease, can also reduce blink frequency. Local pathology of the eyelids, such as ptosis, chalazia and carcinomas, can alter eyelid function and movement, and hence interfere with normal blinking activity. It is therefore essential to rule out the possibility of unrelated pathology before ascribing blinking dysfunction to contact lens wear.

PTOSIS

The classical appearance of ptosis is of a narrowing of the palpebral fissure and a relatively large gap between the upper-lid margin and the skin fold at the top of the eyelid (Fig. 40.2). Fonn et al. (1996) measured the palpebral aperture size to be 10.10 ± 1.11 mm in non-wearers and 9.76 ± 0.99 mm in rigid lens wearers; it was unaltered in soft lens wearers. According to van den Bosch and Lemij (1992), clinically significant ptosis occurs when the distance between the centre of the pupil and the lower margin of the upper lid is less than 2.8 mm. Using this criterion, contact-lens-induced ptosis (CLIP) occurs in about 10% of rigid lens wearers (van den Bosch and Lemij, 1992). The ptosis takes 4–6 weeks to develop fully, and is generally noticed by patients in advanced cases. There are no associated signs or symptoms.

A number of mechanisms have been advanced as possible causes of CLIP. Those involving some form of dysfunction of the aponeurosis include forced-lid repeated squeezing and lateral

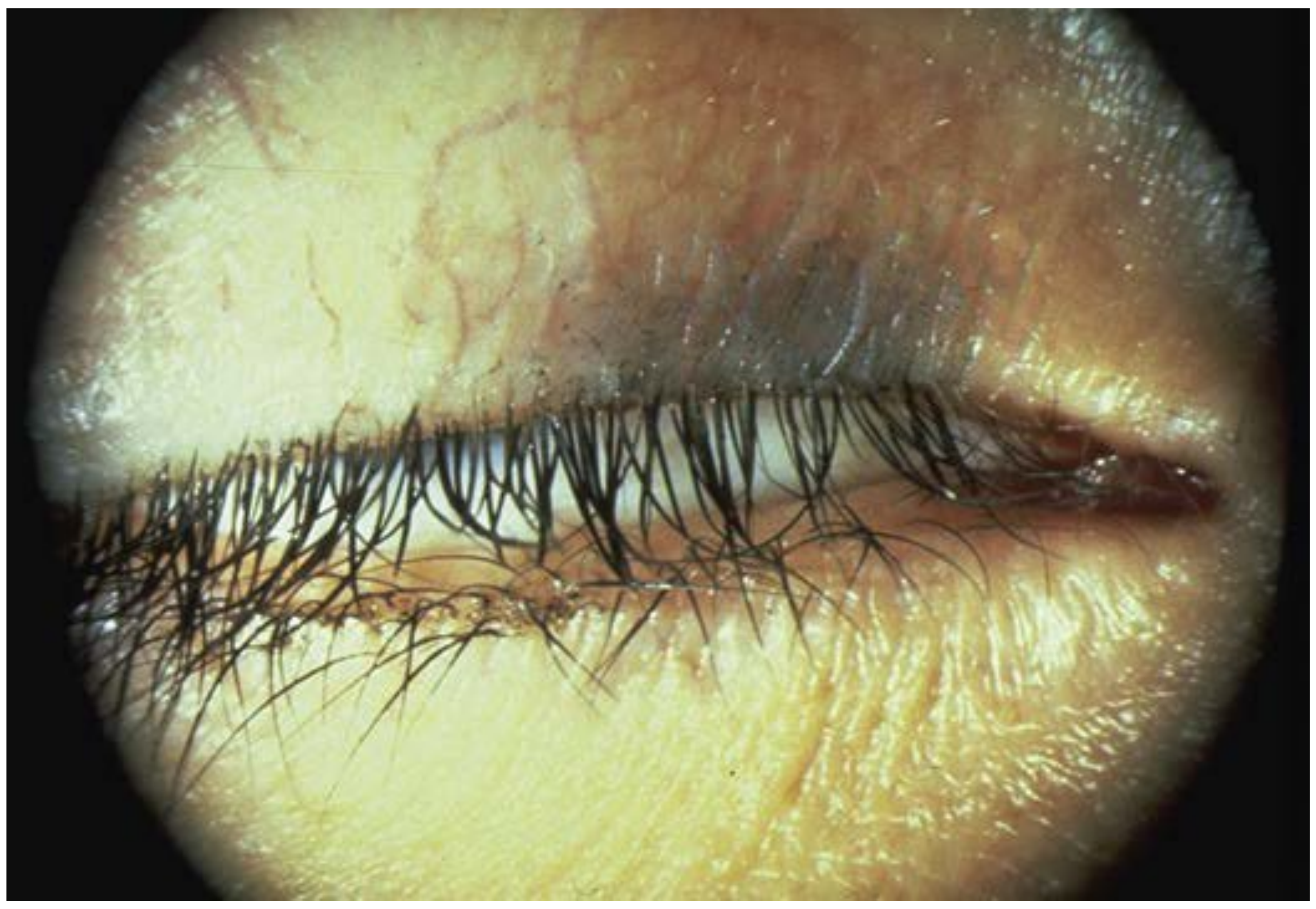

Fig. 40.1 Incomplete blink in a soft lens wearer. (Courtesy of Hilmar Bussaker, Bausch & Lomb Slide Library.)

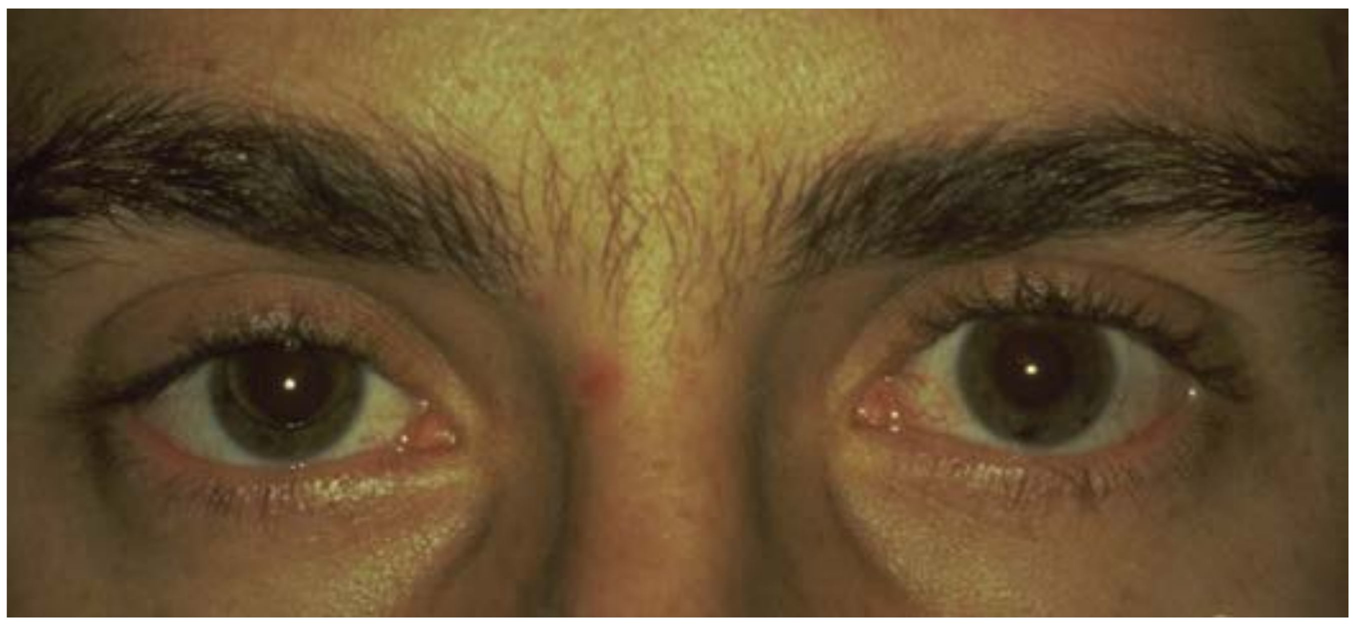

Fig. 40.2 Unilateral right-eye ptosis induced by the wearing of a rigid lens in the right eye for 4 weeks on an extended-wear basis; the left eye wore a soft lens. Note that the gap between the skin fold (just beneath the eyebrows) and the upper-lid margin is greater in the right eye than the left. (Courtesy of Desmond Fonn, Bausch & Lomb Slide Library.)

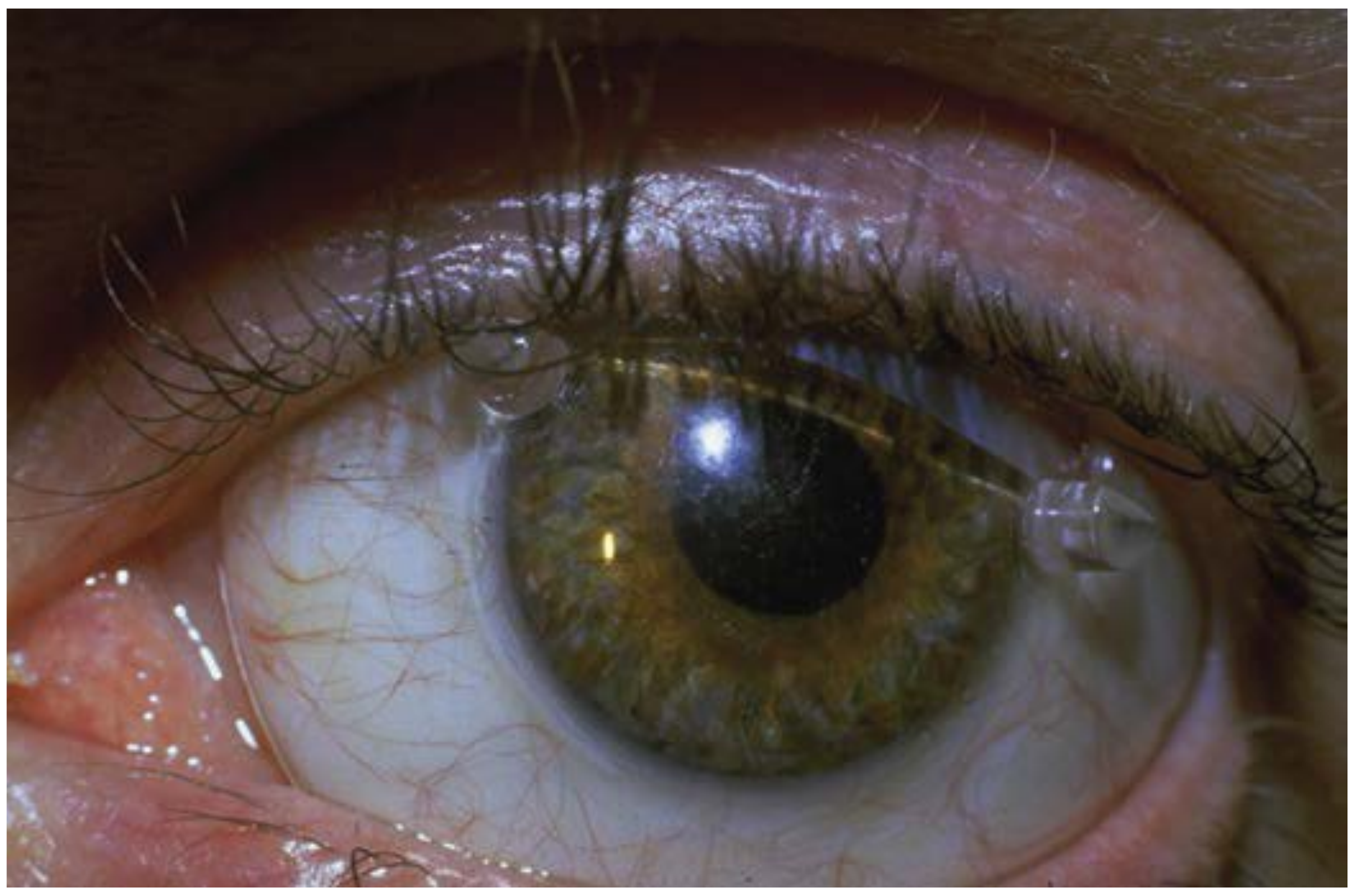

Fig. 40.3 Scleral lens with 'ptosis crutch' in the form of two lugs and a shelf. (Courtesy of Frank Pettigrew.)

eyelid stretching during lens removal, rigid lens displacement of the tarsus and blink-induced eye rubbing (Fujiwara et al., 2001). Non-aponeurogenic causes of CLIP include lens-induced lid oedema, blepharospasm and papillary conjunctivitis. Watanabe et al. (2006) suggest that CLIP is often attributable to fibrosis in Müller muscle.

To differentiate between these possible causes, patients demonstrating CLIP should be required to cease lens wear for at least 1 month (to detect any trends towards recovery) and perhaps as long as 3 months (to demonstrate complete resolution). If the CLIP partially or completely resolves after ceasing lens wear for 1 month, then the cause is lid oedema and/or involuntary blepharospasm, and the patient may need to be refitted with soft lenses (which do not induce ptosis). The eyelids should also be inverted to determine whether papillary conjunctivitis is involved and, if so, whether appropriate action should be taken to alleviate the condition. If the ptosis persists after resolution of the papillary conjunctivitis, or after ceasing lens wear for 1 month, then the cause is most likely damage to the aponeurosis or Müller muscle, whereby surgical correction is the preferred option. Management strategies available to patients with severe CLIP who do not wish to undergo lid surgery include being fitted with a 'ptosis crutch' (Fig. 40.3).

The prognosis for recovery from aponeurogenic CLIP is poor; the condition can be reversed only by surgical correction or by other management options as described above. The prognosis for recovery from non-aponeurogenic CLIP is good. If the cause of ptosis is papillary conjunctivitis, the time course of resolution of the ptosis will parallel the time course of recovery of the papillary conjunctivitis.

If a contact lens wearer presents with ptosis, the numerous other possible causes of this condition must be considered so that the appropriate course of management can be adopted.

MEIBOMIAN GLAND DYSFUNCTION

Meibomian gland dysfunction (MGD) is defined as a chronic, diffuse abnormality of the meibomian glands, commonly characterized by terminal duct obstruction and/or qualitative/quantitative changes in the glandular secretion. It may result in alteration of the tear film, symptoms of eye irritation, clinically apparent inflammation, and ocular surface disease (Nichols et al., 2011).

MGD is classified into two major categories based on meibomian gland secretion: low-delivery states and high-delivery states. Low-delivery states are further classified as hyposecretory or obstructive, with cicatricial and non-cicatricial subcategories. Hyposecretory MGD describes the condition of decreased meibum delivery due to abnormalities in meibomian glands without remarkable obstruction. Obstructive MGD is due to terminal duct obstruction. In the cicatricial form, the duct orifices are dragged posteriorly into the mucosa, whereas these orifices remain in their normal positions in non-cicatricial MGD. High-delivery, hypersecretory MGD is characterized by the release of a large volume of lipid at the lid margin that becomes visible on application of pressure onto the tarsus during examination. Overall, MGD can lead to alterations of the tear film, symptoms of eye irritation, inflammation and dry eye (Nichols et al., 2011).

Tear film lipids are essential for ease and comfort in contact lens wear, but also form deposits on lenses. It is possible that contact lens wear itself disrupts the meibomian glands and/or lipid layer and leads to tear film evaporation and ocular surface discomfort.

The oily secretion from the normal meibomian gland is generally clear. One diagnostic feature of contact-lens-associated meibomian gland dysfunction (CL-MGD) is a change in the appearance of the clear oil expressed from healthy meibomian glands to a cloudy, creamy-yellow appearance (Fig. 40.4).

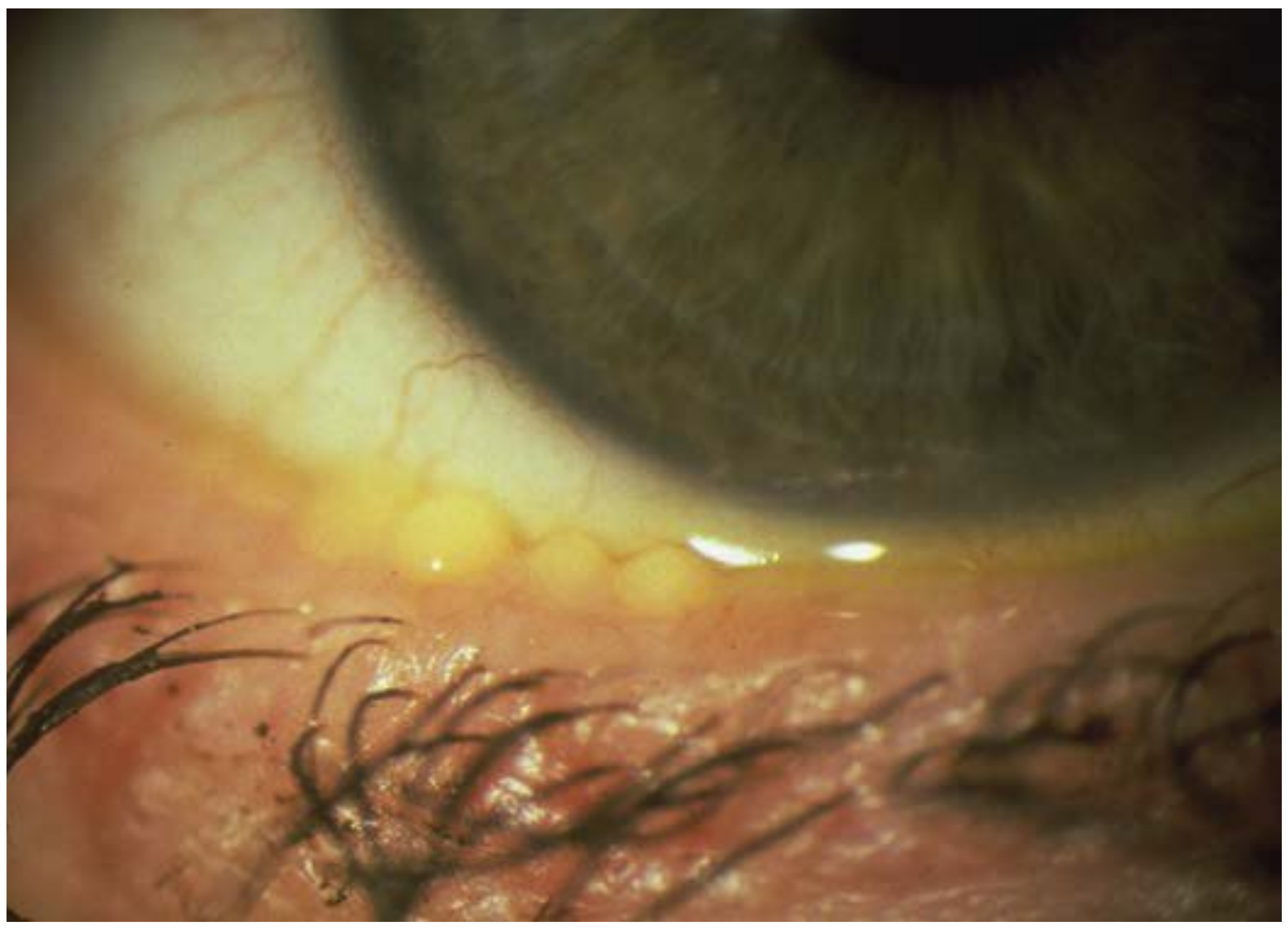

Fig. 40.4 Inspissated meibomian gland secretion in the lower lid of a female patient wearing rigid lenses. (Courtesy of Lyndon Jones, Bausch & Lomb Slide Library.)

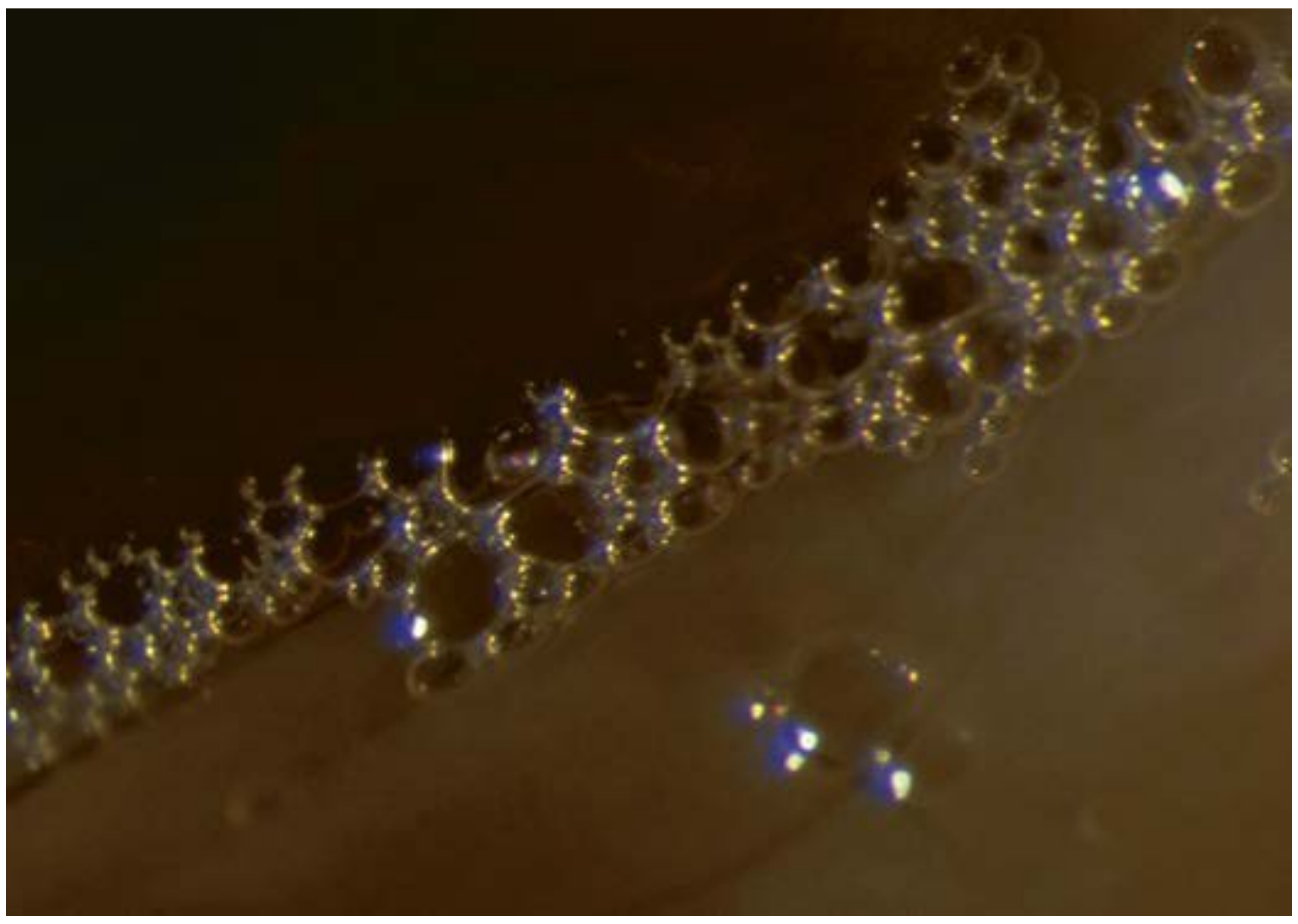

Fig. 40.5 Frothing in the tear film due to meibomian gland dysfunction. (Courtesy of Lourdes Llobet, Bausch & Lomb Slide Library.)

Frothing or foaming of the lower tear meniscus is sometimes observed in CL-MGD, especially towards the outer canthus (Fig. 40.5). This appearance is accompanied by symptoms of smeary vision, greasy lenses, dry eyes and reduced tolerance to lens wear (Ong, 1996). In severe cases where the meibomian orifices are blocked, there may be an absence of gland secretion. Long-standing cases of CL-MGD may be associated with additional signs such as irregularity, distortion and thickening of eyelid margins, slight distension of glands, gland drop-out, mild to moderate papillary hypertrophy, vascular changes and chronic chalazia. The prevalence of CL-MGD is unrelated to gender but increases with age.

Associated signs of CL-MGD include all those which arise from clinical diagnostic procedures that are designed to indicate the integrity or otherwise of the lipid layer. Specifically, patients suffering from CL-MGD may display a reduced tear break-up time (measured either with fluorescein or non-invasively). Examination of the tear layer in specular reflection using a Tearscope may reveal a contaminated lipid pattern, which is exacerbated by the use of cosmetic eye make-up. Symptoms of blurred or greasy vision can probably be attributed to adhesion of waxy dysfunctional meibomian oils to the surface of the contact lens; this can lead to lens surface drying, lens dehydration and sensations of dryness.

There is probably no single cause of CL-MGD; proposed aetiological factors include excess eye rubbing causing chronic damage to meibomian glands, and papillary conjunctivitis. From a tissue pathology standpoint, obstructive MGD is characterized by increased keratinization of the epithelial walls of meibomian gland ducts. As might be expected, therefore, this condition is often observed in combination with seborrhoeic dermatitis and acne rosacea. This leads to the formation of keratinized epithelial plugs that create a physical blockage in meibomian ducts, which in turn restricts or prevents the outflow of meibomian oils. Arita et al. (2009) have shown that contact lens wear is associated with a decrease in the number of functional meibomian glands, and that this decrease is proportional to the duration of lens wear.

Although it may not be possible to treat the underlying cause of CL-MGD symptomatic relief can be provided by adopting one or more of the following procedures, all of which should be undertaken with contact lenses removed:

- application of warm compresses
- lid scrubs
- mechanical expression
- prescription of antibiotics
- use of artificial tears
- omega-3 dietary supplements
- use of surfactant lens cleaners.

By adopting these procedures, CL-MGD can be kept under good control and adverse symptoms minimized (Paugh et al., 1990; Macsai, 2008).

LID WIPER EPITHELIOPATHY

The lid wiper is a thin strip of tissue near the lid margin that is in contact with the ocular surface or anterior lens surface (where contact lenses are worn). It is responsible for spreading tears across the ocular surface during blinking (Korb et al., 2002). In the upper eyelid, the lid wiper extends about 0.6 mm from the crest of the sharp posterior (inner) lid border (i.e. the mucocutaneous junction, or line of Marx) to the subtarsal fold superiorly and from the medial upper punctum to the lateral canthus horizontally (Efron et al., 2016).

Histologically, the lid wiper is seen as an epithelial elevation comprising stratified epithelium with a conjunctival structure of cuboidal cells, some parakeratinized cells and goblet cells (Efron et al., 2016). Lid wiper epitheliopathy denotes staining of the lid wiper after instillation of dyes such as fluorescein, rose bengal or lissamine green. Although Korb et al. (2002) advocate the use of a simultaneous combination two dyes to stain the lid wiper, most clinicians and researchers seem to favour the use of lissamine green alone (Efron et al., 2016).

Higher rates of lid wiper epitheliopathy have been reported in dry-eye patients and contact lens wearers; however, published evidence supporting these observations is sometimes conflicting (Efron et al., 2016). The primary cause of lid wiper epitheliopathy is thought to be increased friction between the lid wiper and ocular or anterior contact lens surface due to inadequate lubrication, which could be caused by dry eye and may be exacerbated by factors such as abnormal blinking patterns, poor contact lens surface lubricity and adverse environmental influences (Korb et al., 2002). Lid wiper epitheliopathy may be associated with subclinical inflammation (Alzahrani et al., 2016).

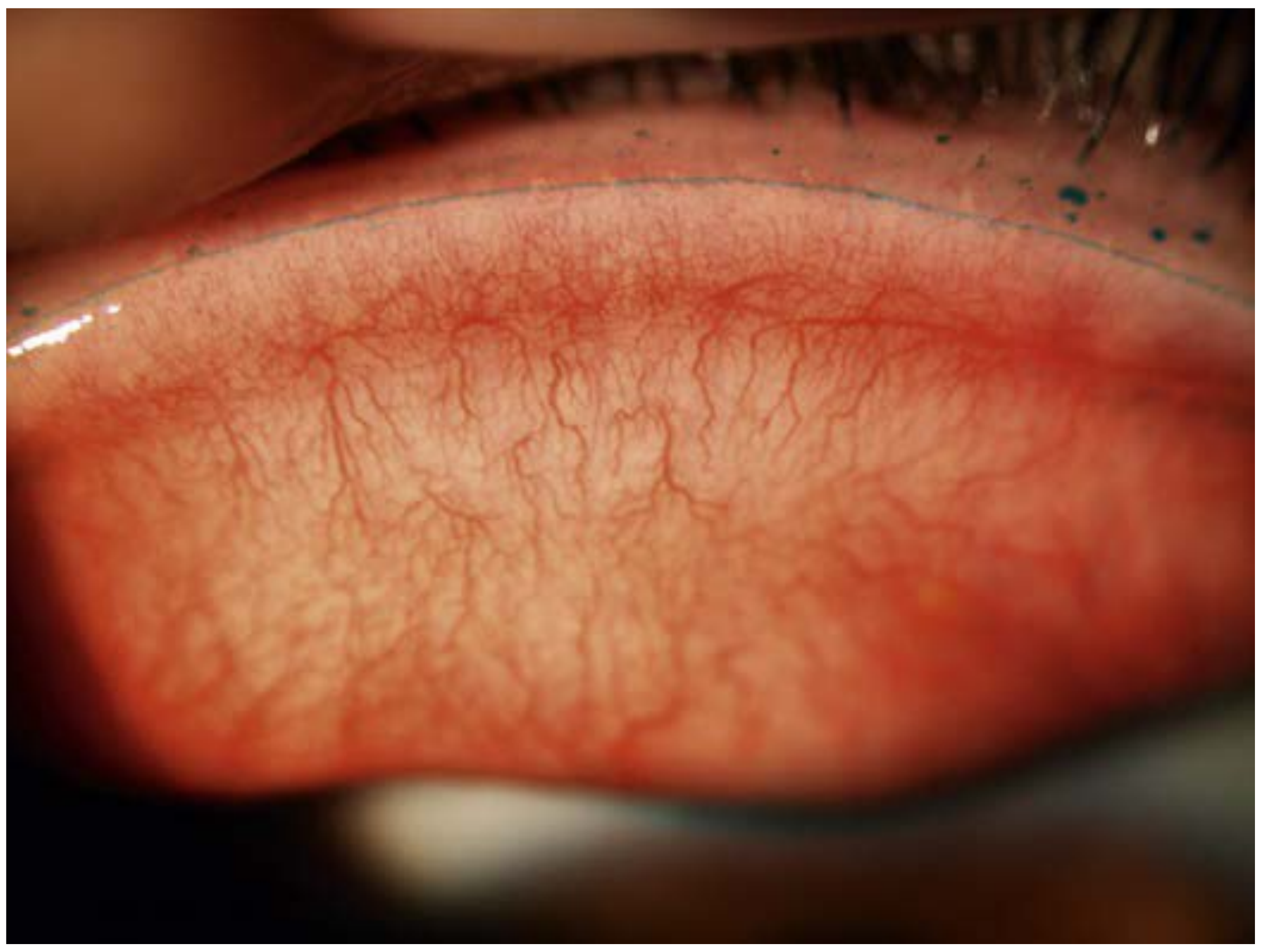

Fig. 40.6 Normal appearance of the mucocutaneous junction (line of Marx) observed at the lid margin as a fine green line following instillation of lissamine green. (Image courtesy of Maria Navascues Cornago.)

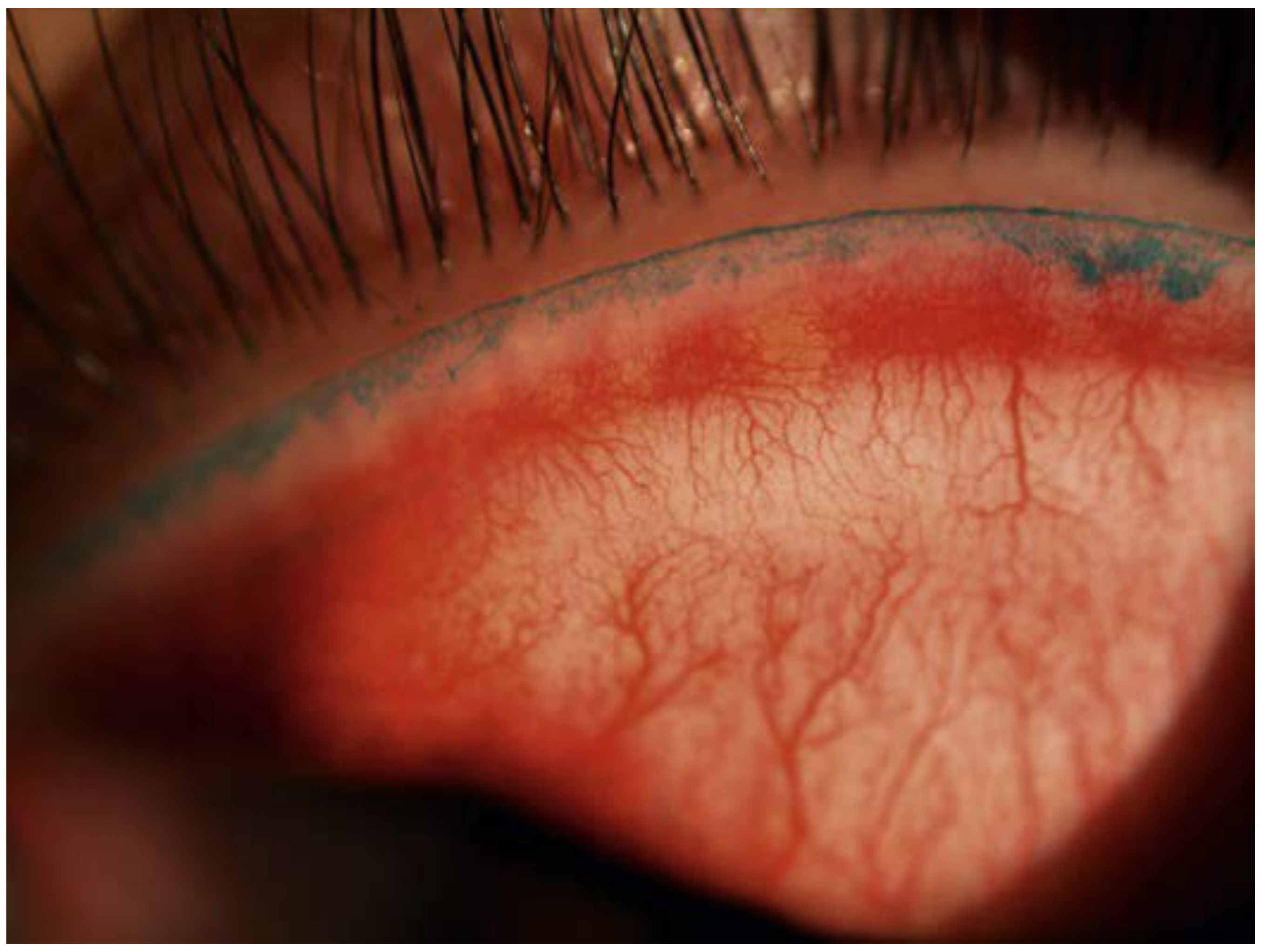

Fig. 40.7 Lid wiper epitheliopathy revealed by lissamine green staining in the everted eyelid. A broad band of staining extends below the clearly visible line of Marx. Staining is apparent across the full lateral width of the lid wiper. (Image courtesy of Maria Navascues Cornago.)

The optimal procedure for observing lid wiper epitheliopathy is to use a paper strip impregnated with 1 mg lissamine green. The paper strip is moistened with 50 µl of saline and applied to the eye. This procedure is repeated 1 minute later. The eyelid is everted 3 minutes after the second instillation to visualize the lid wiper. It is important to differentiate between normal staining of the line of Marx – a 0.1 mm wide strip that constitutes the region of the mucocutaneous junction of the upper and lower lids that is essentially located along the distal margin of the lid wiper (Fig. 40.6) – and lid wiper epitheliopathy (Fig. 40.7). The line of Marx is visible with lissamine green staining in upgaze without lid eversion, whereas observation of the lid wiper requires lid eversion.

Management of severe lid wiper epitheliopathy is indicated if the patient is experiencing moderate to severe discomfort. The management strategy adopted will depend on the cause of the condition, which is not always obvious. Treatment options that have been advocated include the following:

- rebamipide – this is an amino acid derivative of 2-(1H)-quinolinone and is used for mucosal protection, healing of gastroduodenal ulcers and treatment of gastritis. Administration of topical rebamipide increases secretion of mucins from goblet cells and improves the ocular surface in the 'short break-up time' type of dry eye
- corticosteroids
- lubricant eye drops
- basic fibroblast growth factor
- LipiFlow Thermal Pulsation System
- punctal plugs
- fit contact lenses of high surface lubricity
- alter lens wearing modalities – such as reducing lens wearing time, increasing lens replacement frequency, changing lens material properties (modulus of elasticity, silicone/water content, surface-active agents or packaging wetting agents)
- improve blinking behaviour.

EYELASH DISORDERS

Disorders of the eyelashes (cilia), and of associated structures at the base of the eyelashes such as the eyelash follicles, glands of Zeis and Moll, and skin of the lid margin, have implications with respect to contact lens wear. An external hordeolum (stye) presents as a discrete, tender swelling of the anterior lid margin; specifically, it is an inflammation of the tissue lining the lash follicle and/or an associated gland of Zeis or Moll. Contact lenses may add to the discomfort due to the mechanical effect of the lens, and patients may prefer to cease lens wear during the acute phase of the formation of a stye.

Blepharitis is classified as being either anterior or posterior. Posterior blepharitis is a disorder of the meibomian glands; this was considered earlier. Anterior blepharitis is directly related to infections of the base of the eyelashes and manifests in two forms – staphylococcal and seborrhoeic. Staphylococcal anterior blepharitis is caused by a chronic staphylococcal infection of the eyelash follicles. The lid margins are covered in shiny brittle scales (Fig. 40.8), and patients may complain of burning, dryness, itching, foreign-body sensations and mild photophobia. Management strategies include antibiotic ointment, promoting lid hygiene (Keys, 1996), application of weak topical steroids and artificial tears. Seborrhoeic anterior blepharitis is due to a disorder of the glands of Zeis and Moll. The signs and symptoms are similar but less severe than for staphylococcal anterior blepharitis.

Contact lens wear is generally contraindicated during an acute phase of anterior blepharitis, especially if the cornea is compromised. Attention to lens cleaning is critical to prevent continued recontamination of the eye. Daily disposable contact lenses will eliminate the problem of recontamination by contact lenses.

Infestation of the eyelashes by mites or lice can lead to signs and symptoms that closely resemble marginal blepharitis. Typical symptoms include pruritus, burning, crusting, itching, swelling of the lid margins and loss and easy removal of lashes. The itching often parallels the 10-day mite reproductive cycle.

The pubic or 'crab' louse (Phthirus pubis) has two pairs of strong grasping claws on the central and hind legs, allowing it

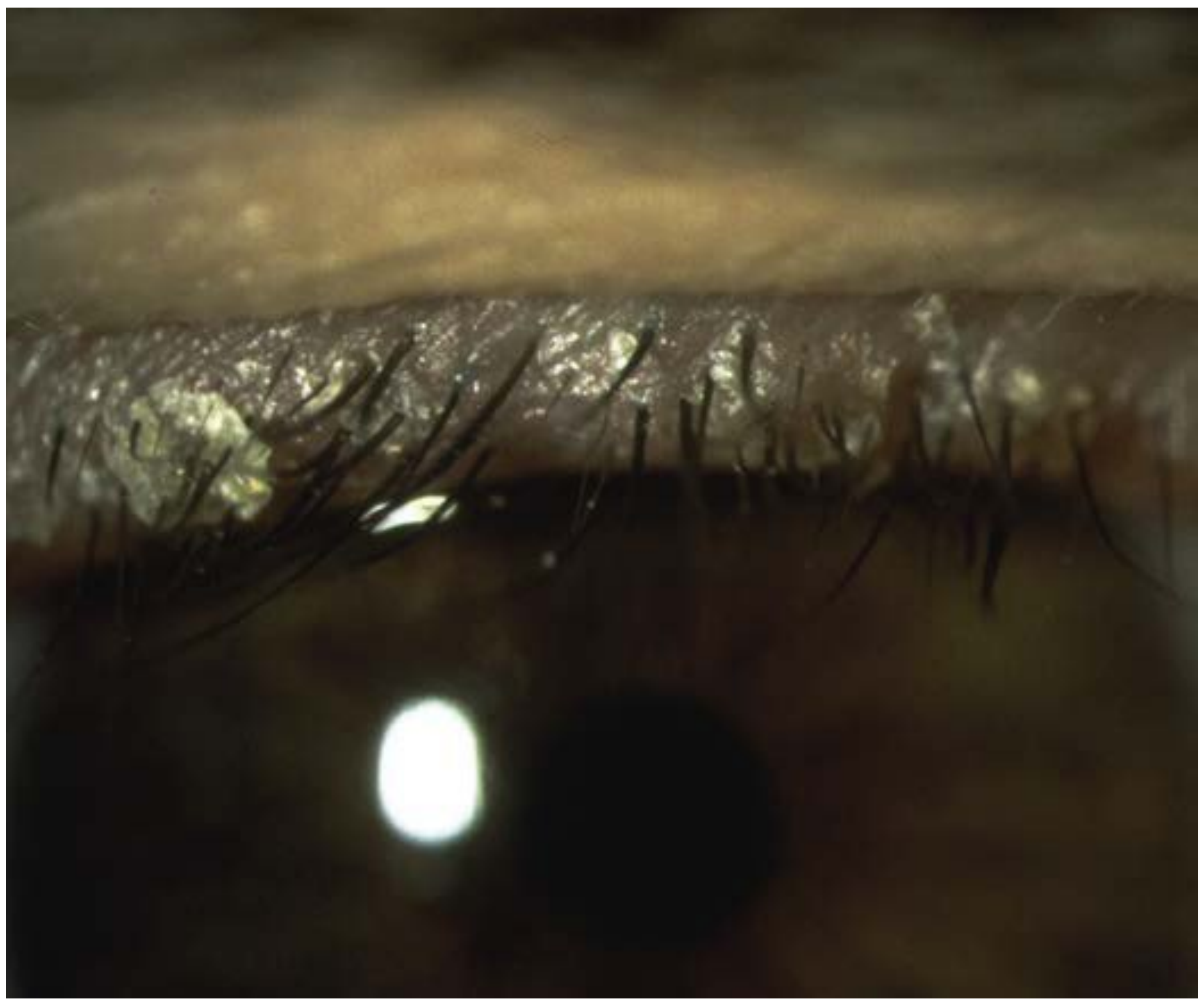

Fig. 40.8 Staphylococcal anterior blepharitis. (Courtesy of Debbie Jones, Bausch & Lomb Slide Library.)

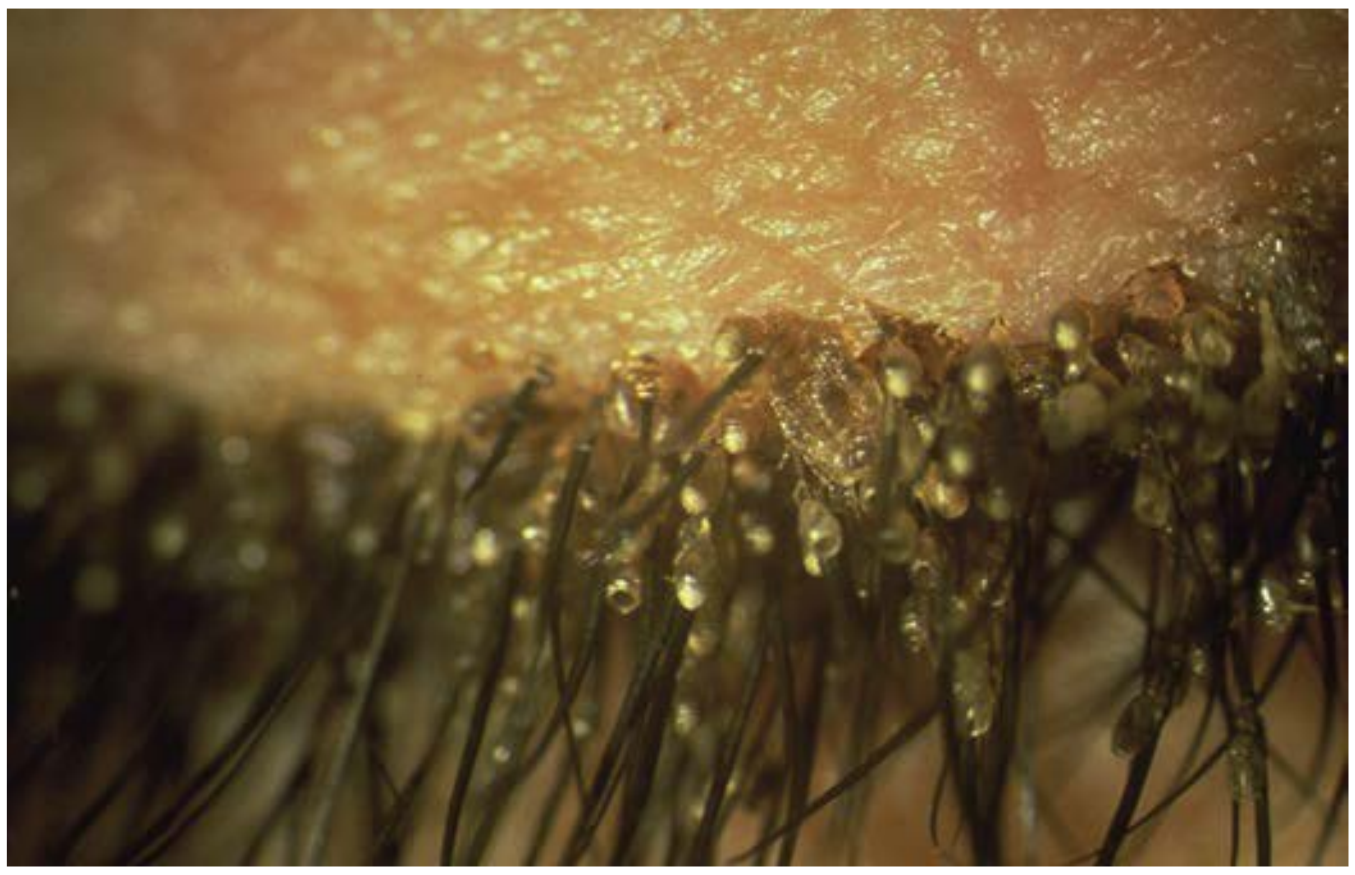

Fig. 40.9 A nearly transparent crab louse can be seen at the root of the lashes, surrounded by nits encapsulated in shells, and some empty shells. (Courtesy of Patrick Caroline, Bausch & Lomb Slide Library.)

to hold on to eyelashes with considerable tenacity. Crab louse infestation (phthiriasis) is considered to be a venereal disease because it is passed on by sexual contact, although infestation from contaminated bedding and towels is another possible mode of transfer.

Signs of phthiriasis include pruritus of the lid margins, blepharitis, marked conjunctival injection, madarosis and the presence of lice as well as oval, greyish-white nit shells attached to the base of lashes (Fig. 40.9). Additional signs include preauricular lymphadenopathy and secondary infection along the lid margins at the site of lice bites. The most predominant symptom is intense itching. The initial course of action is to attempt to remove as many mites and mite eggs as possible. Patients should be advised to engage in vigorous lid scrubbing twice daily using commercially available preparations. In general, contact lens wearers presenting with parasitic infestation of the eyelids should be treated in the same way as similarly infested non-lens-wearers (Caroline et al., 1991).

Tear Film

The functions of the tear film during contact lens wear can be categorized as follows:

- Optical – the tear film maintains an optically uniform interface between the air and the anterior surface of the lens.
- Mechanical – the tear film acts as a vehicle for the continual blink-mediated removal of intrinsic and extrinsic debris and particulate matter from the front of the lens and from beneath the lens.
- Lubricant – the tear film ensures a smooth movement of the eyelids over the front surface of the lens, and of the lens over the globe, during blinking.
- Bactericidal – the tear film contains defence mechanisms in the form of proteins, antibodies, phagocytotic cells and other immunodefence mechanisms that prevent contact-lens-induced infection.
- Nutritional – the tear film supplies the corneal epithelium with necessary supplies of oxygen, glucose, amino acids and vitamins beneath contact lenses via the lid–lens tear pump.
- Waste removal – the tear film acts as an intermediate reservoir for the removal of corneal metabolic byproducts, such as carbon dioxide and lactate, from beneath the lens via the lid–lens tear pump.

This section will outline how these functions can be compromised during lens wear, leading to the primary problem of dryness and the secondary problem of mucus ball formation. Techniques for detecting and resolving these problems are also considered.

DRY EYE

Of all the symptoms experienced by contact lens wearers, that of 'dryness' is reported most frequently (Brennan and Efron, 1989); about half of all wearers have symptoms of dryness and discomfort (Fonn, 2007). A major difficulty in assessing the symptom of 'dryness' is that there may be many stimuli that elicit this sensation – that is, it cannot be assumed that the cause of a patient symptom of 'dryness' is necessarily due to the eye being dry. Because there are no specific 'dryness receptors' in human tissue, ocular dryness must be a response to specific coding of afferent neural inputs. Aside from an actual dry eye, reports of 'dryness' may arise from the neural misinterpretation of stimuli that are unrelated to dry eye, such as vasodilation induced by mechanical irritation of ocular tissues by deposits on the lens surface. Thus, the condition of 'dry eye' may be related to a broad spectrum of tear film abnormalities in addition to a reduced tear volume.

A prudent initial approach in dealing with a tentative diagnosis of contact-lens-induced dry eye is to apply a comprehensive questionnaire that draws in other systemic correlates of dryness, such as dryness of other mucous membranes of the body, use of medications, effect of different challenging environments and times when dryness is noted. Such questionnaires can help identify a true dry-eye situation in prospective or current contact lens wearers and thus form a clinical rationale for more detailed assessment.

The most fundamental test that a clinician can apply when investigating dry eye is to observe the tear film and adjacent ocular structures using the slit-lamp biomicroscope. The overall integrity of the tears during lens wear can be assessed by observing the general flow of tears over

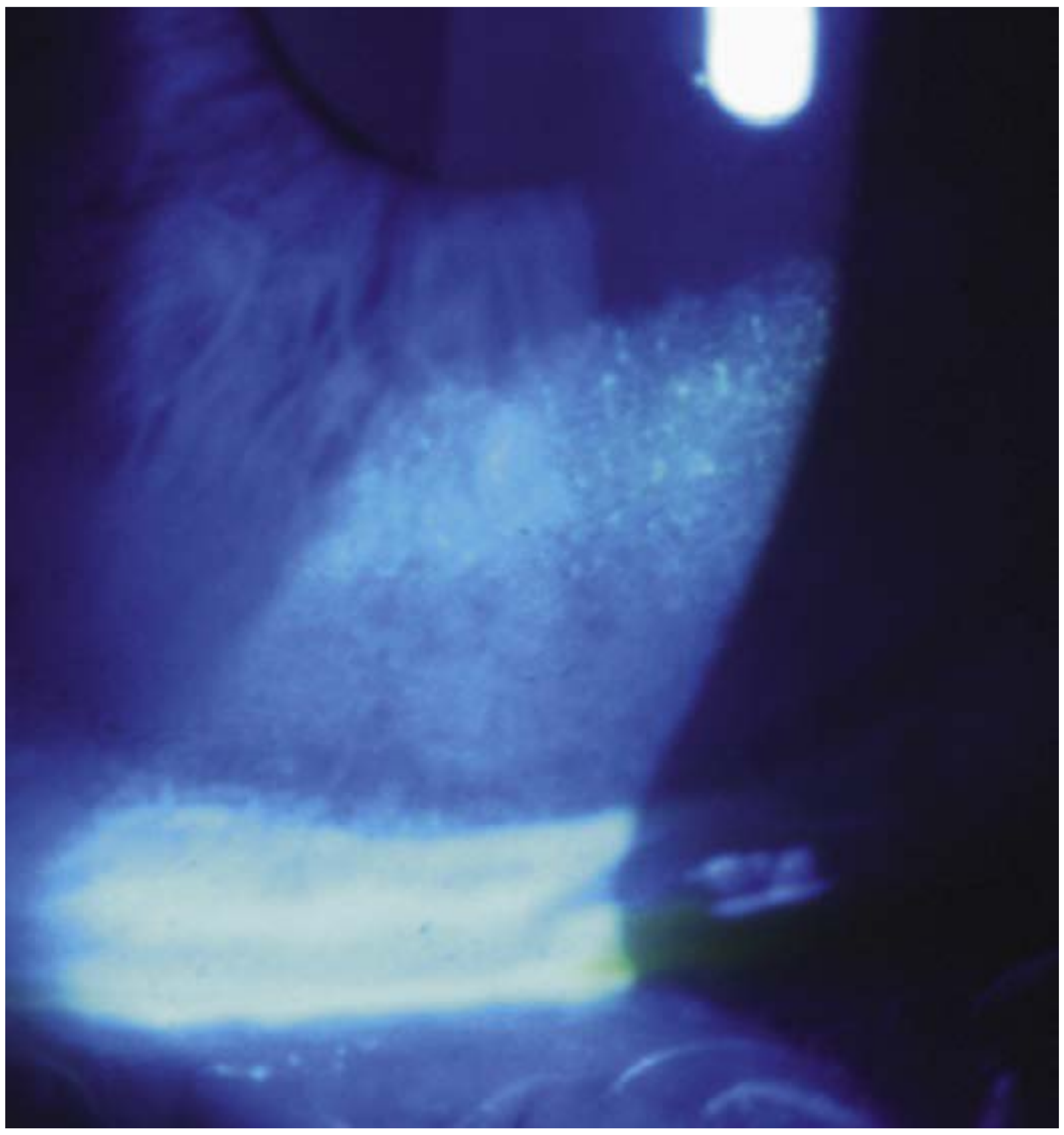

Fig. 40.10 Inferior desiccation staining in a patient wearing soft lenses and suffering from dry-eye symptoms. (Courtesy of Michael Hare.)

the lens surface following a blink, as indicated by the movement of tear debris. A sluggish movement may indicate an aqueous-deficient, mucus-rich and / or lipid-rich tear film, and the amount of debris provides an indication of the level of contamination of the tears – for example, from overuse of cosmetics. A sluggish and / or contaminated tear film is potentially problematic, and could result in increased deposit formation, intermittent blurred vision and symptoms of dryness. Incomplete blinking in soft lens wearers can lead to lens dehydration and consequent epithelial staining of the inferior cornea, corresponding to the position of the palpebral aperture (Fig. 40.10).

The volume of tears in prospective and current contact lens wearers can be assessed by observing the height of the lower lacrimal tear prism. Mainstone et al. (1996) found that measurements of tear meniscus radius of curvature and height (Fig. 40.11) correlated well with results of the cotton thread test, non-invasive tear break-up time and ocular-surface-staining scores, demonstrating the value of such an assessment in diagnosing contact-lens-associated dry eye. Tear volumes in dry-eye symptomatic wearers are lower than in asymptomatic wearers, resulting in the sensation of dryness (Chen et al., 2009). A wide-field, cold cathode light source, which is available as a hand-held instrument known as a Tearscope, can be used to assess tear quality during lens wear.

Most of the strategies that are applied to alleviating signs and symptoms of dry eye of the non-lens-wearing eye can also be applied to the eye during contact lens wear. In the first instance, attention should be directed to managing the underlying cause if this is known. For example, alleviating CL-MGD, lid wiper epitheliopathy or papillary conjunctivitis (all of which are dealt with elsewhere in this chapter) may lead to a diminution of dry-eye symptoms.

The characteristics of a contact lens that is most suited for a patient experiencing dry-eye problems are as follows:

- a soft lens – with a highly lubricious (low friction) surface and providing full corneal coverage (although some patients report relief from dry-eye symptoms after changing from a soft to a rigid lens)
- a lens that displays minimal in-eye dehydration – to prevent ocular surface desiccation
- a lens that is replaced frequently – for optimal, deposit-free surface characteristics.

Numerous other strategies have been advocated for alleviating dry eye, including avoidance of preservatives in care solutions, avoidance of solutions altogether via the use of 1-day disposable lenses, use of rewetting drops, periodic lens rehydration, use of nutritional supplements, control of evaporation, prevention of excess tear drainage (with punctal plugs), use of tear stimulants, reducing wearing time and ceasing lens wear.

MUCIN BALLS

Approximately 50% of patients who wear silicone hydrogel lenses on an extended-wear basis display a peculiar phenomenon known as mucin balls. These formations can be observed in the post-lens tear film as small discrete particles, or 'plugs', and are similar in appearance to tear film debris. In some patients, as many as 200 mucin balls can be observed. At high magnification (×40), mucin balls can be seen to be of variable size and to take on a characteristic 'flattened doughnut' shape, with a thin circular annulus and broad central depression (Fig. 40.12). They are observed in greater numbers in patients who sleep in silicone hydrogel lenses. Mucin balls are immovable beneath the lens and appear to be stuck to the epithelium. A higher number of mucin balls are associated with a looser lens fit (Dumbleton, 2003). Mucin balls generally increase in number over the first months of lens wear and remain constant thereafter.

Mucin balls cause no discomfort or loss of vision, and appear to be of no immediate consequence with respect to ocular health (Pritchard et al., 2000). However, there may be cause for concern in the long term. Confocal microscopy, with magnification of up to 650×, has shown mucin balls can penetrate the full thickness of the epithelium, leading to activation of keratocytes in the underlying anterior stroma (Efron, 2007). The precorneal mucin layer is also known to be an important defence mechanism against infection, by way of preventing attachment of microorganisms to the corneal surface and facilitating the entrapment and removal of microorganisms in the course of the natural turnover of mucus, whereby the mucus is constantly being aggregated, rolled up and flushed from the eye (Fleiszig et al., 1994). Lens-induced mucin ball production may therefore represent a compromise to this important protective mechanism.

Mucin balls are composed primarily of collapsed mucin, as well as some lipid and tear proteins (Millar et al., 2003). The mechanism by which mucin balls form beneath the lens may in part be related to a physicochemical phenomenon caused by the plasma-treated surface of some types of silicone hydrogel lenses. Specifically, the lipophilic surface of these lenses establishes a complex interfacial relationship with the tear film, which creates a shearing force that has the effect of rolling up tear mucus into small spheres. The mechanical vehicles facilitating such events may be rapid eye movements during sleep and blink-induced lens movement upon awakening. The relatively high modulus of silicone hydrogel

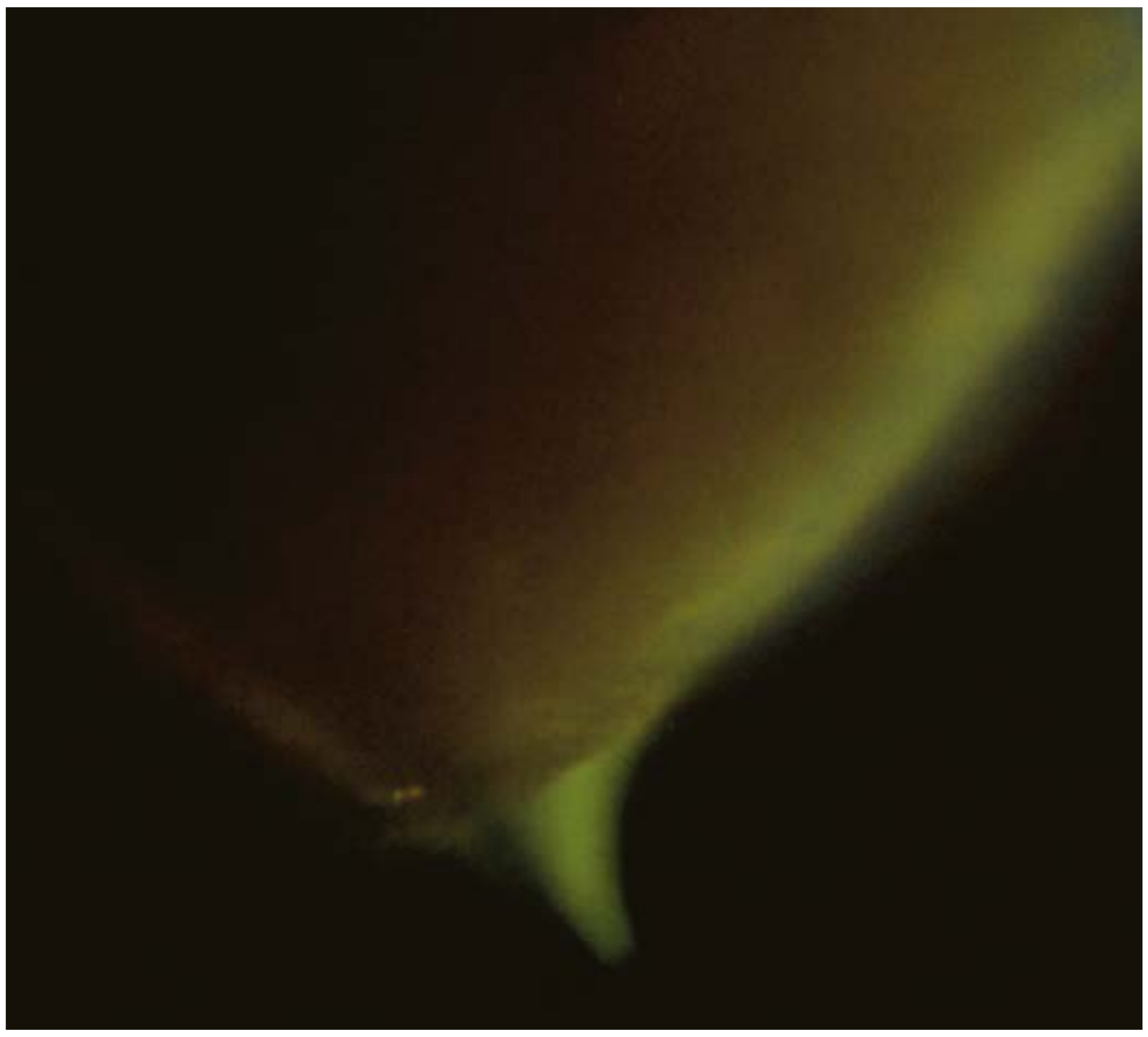

Fig. 40.11 Healthy lower lacrimal tear prism, stained with fluorescein. (Courtesy of Rolf Haberer, Bausch & Lomb Slide Library.)

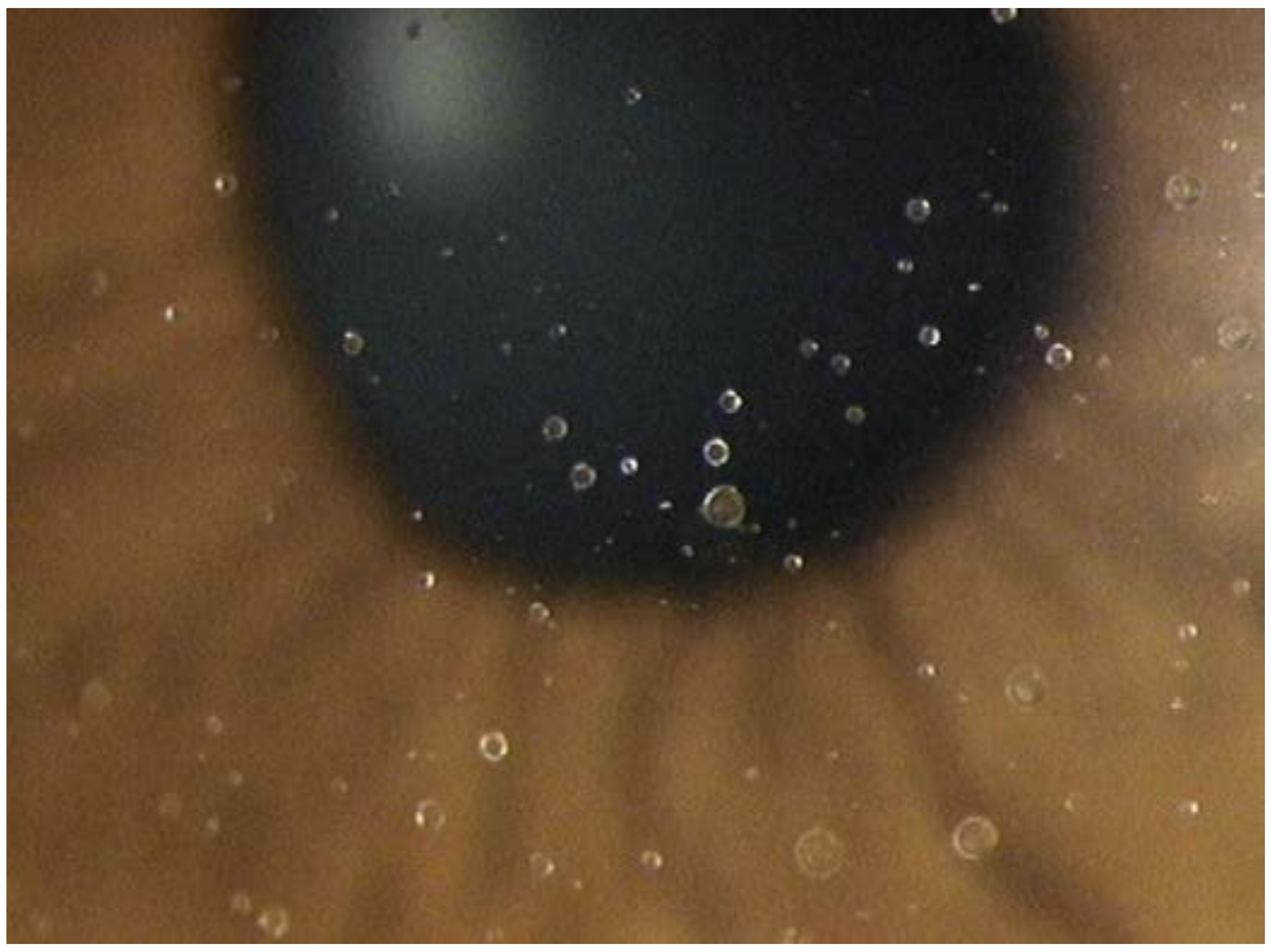

Fig. 40.12 Mucin balls displaying characteristic 'doughnut' appearance. (Courtesy of Brian Tompkins.)

lenses (compared to hydrogel lenses) may also contribute to the above mechanism (Tan et al., 2003). In addition, the more viscous, mucus-rich nature of the closed-eye post-lens tear film is probably of aetiological significance in the formation of mucin balls.

Following lens removal, some mucin balls remain 'stuck' to the epithelium and some are washed away with blinking but leave behind pits in the epithelial surface, which fill with tear aqueous. Both the remaining mucin balls and the surface fluid-filled pits stain with fluorescein (Fig. 40.13). When viewed at ×40 magnification, the fluid-filled pits give rise to the optical phenomenon of unreversed illumination, which is due to the fact that they are composed of a material (tear aqueous) of lower refractive index than the surrounding epithelial tissue (Fig. 40.14). This appearance is almost identical to dimple veiling caused by air bubbles trapped beneath rigid lenses. Mucin ball-induced fluid-filled pits can therefore be differentiated from epithelial microcysts, which display reversed illumination. Mucin-ball-induced fluid-filled pits will stain heavily with fluorescein and give the appearance of an extensive punctate keratitis, whereas epithelial microcysts do not stain except for a few small spots caused by some microcysts breaking through the epithelial surface.

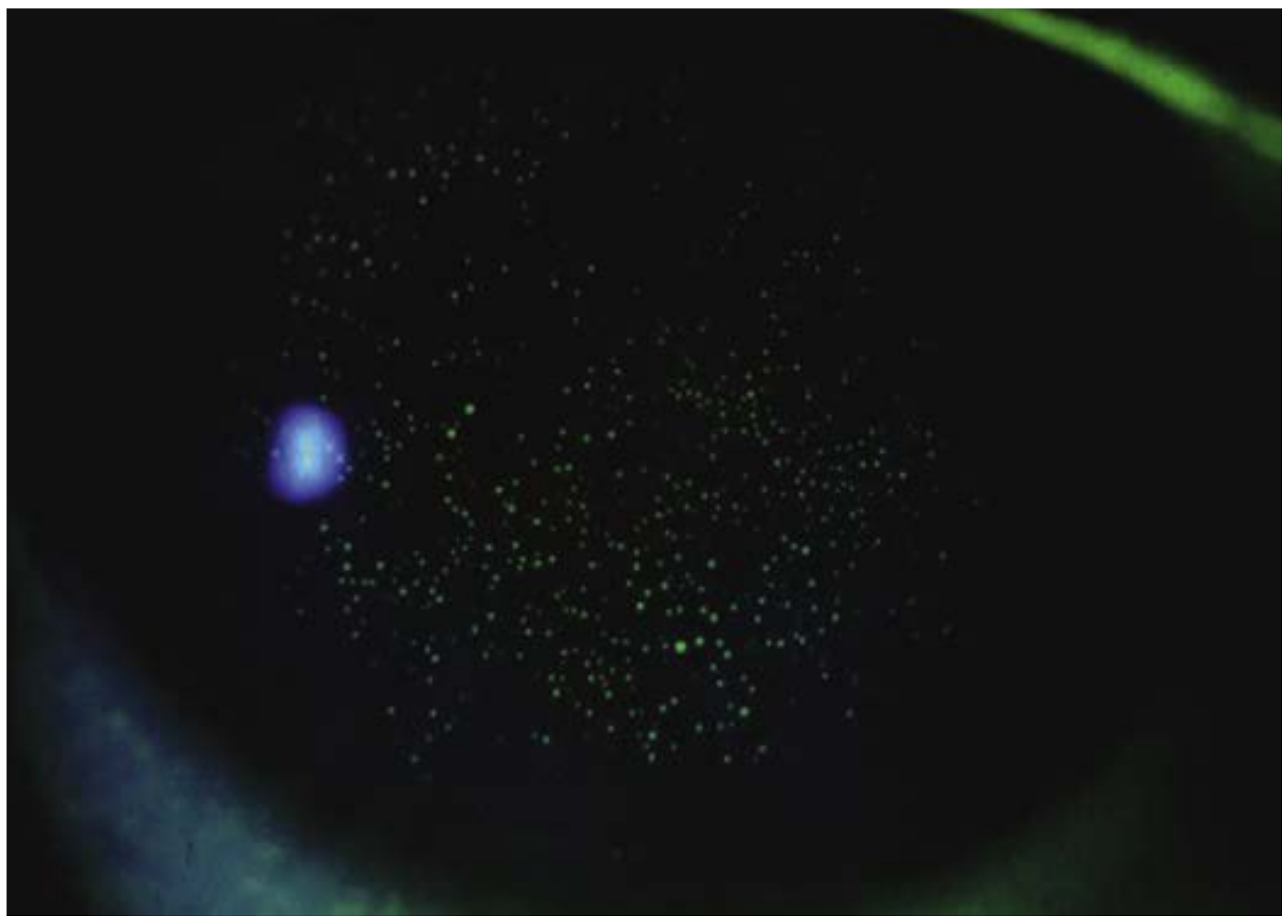

Fig. 40.13 Mucin balls and fluid-filled pits staining with fluorescein. (Courtesy of Kathy Dumbleton, Bausch & Lomb Slide Library.)

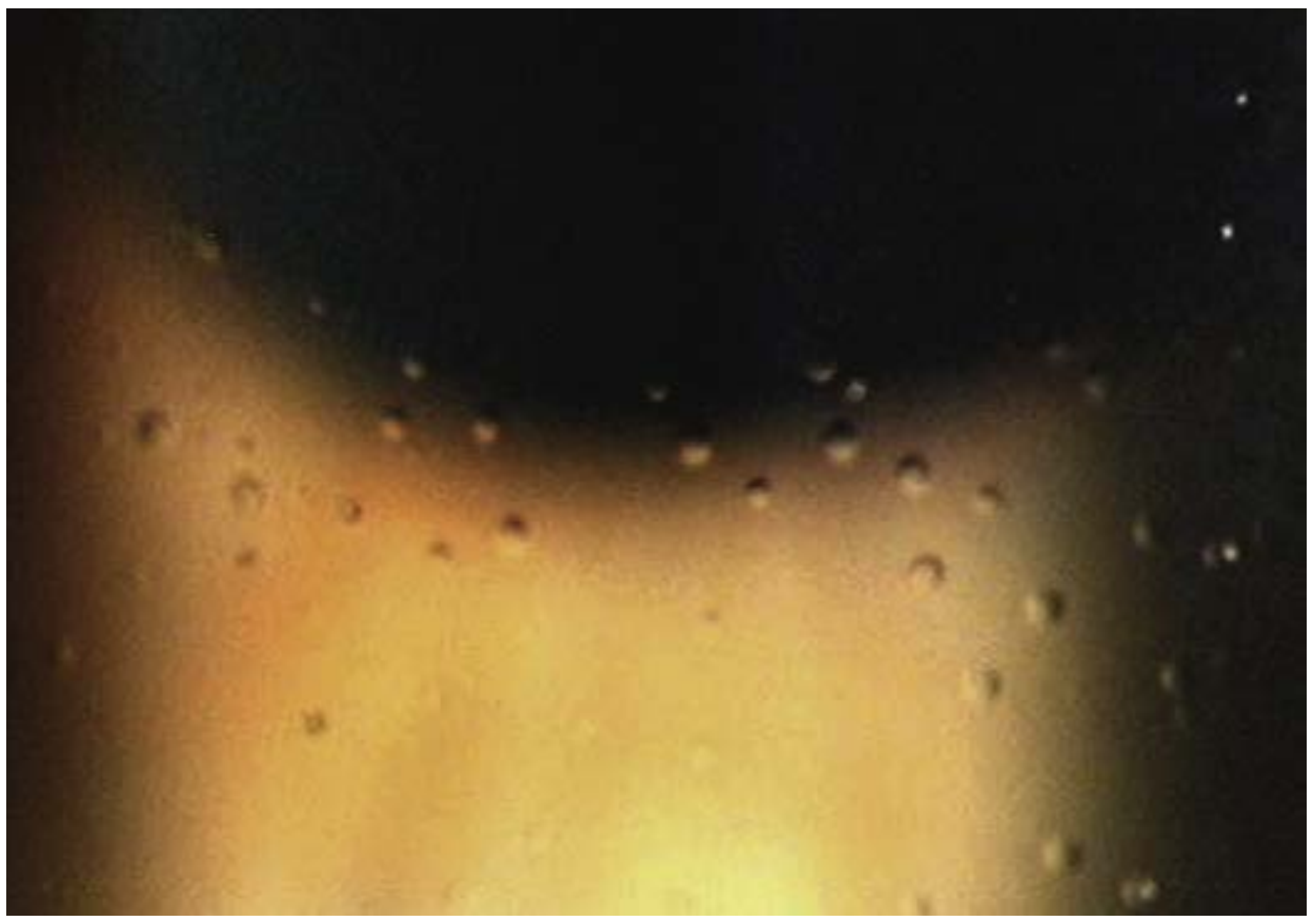

Fig. 40.14 Fluid-filled epithelial pits caused by mucin balls displaying unreversed illumination. (Courtesy of Brian Tompkins.)

Conjunctiva

As a tissue that is in direct apposition with a contact lens, the conjunctiva has an important role to play in the maintenance of successful lens wear. Unlike the cornea, it is a vascularized tissue and is thus capable of mobilizing rapid and often dramatic defence mechanisms, which will in turn serve to resolve the problem and at the same time send a strong signal (e.g. red eye) to the lens wearer and clinician of the existence of a physiological disturbance that requires attention.

CONJUNCTIVAL STAINING

Lakkis and Brennan (1996) evaluated 50 hydrogel lens wearers and 50 non-lens-wearing control subjects for conjunctival

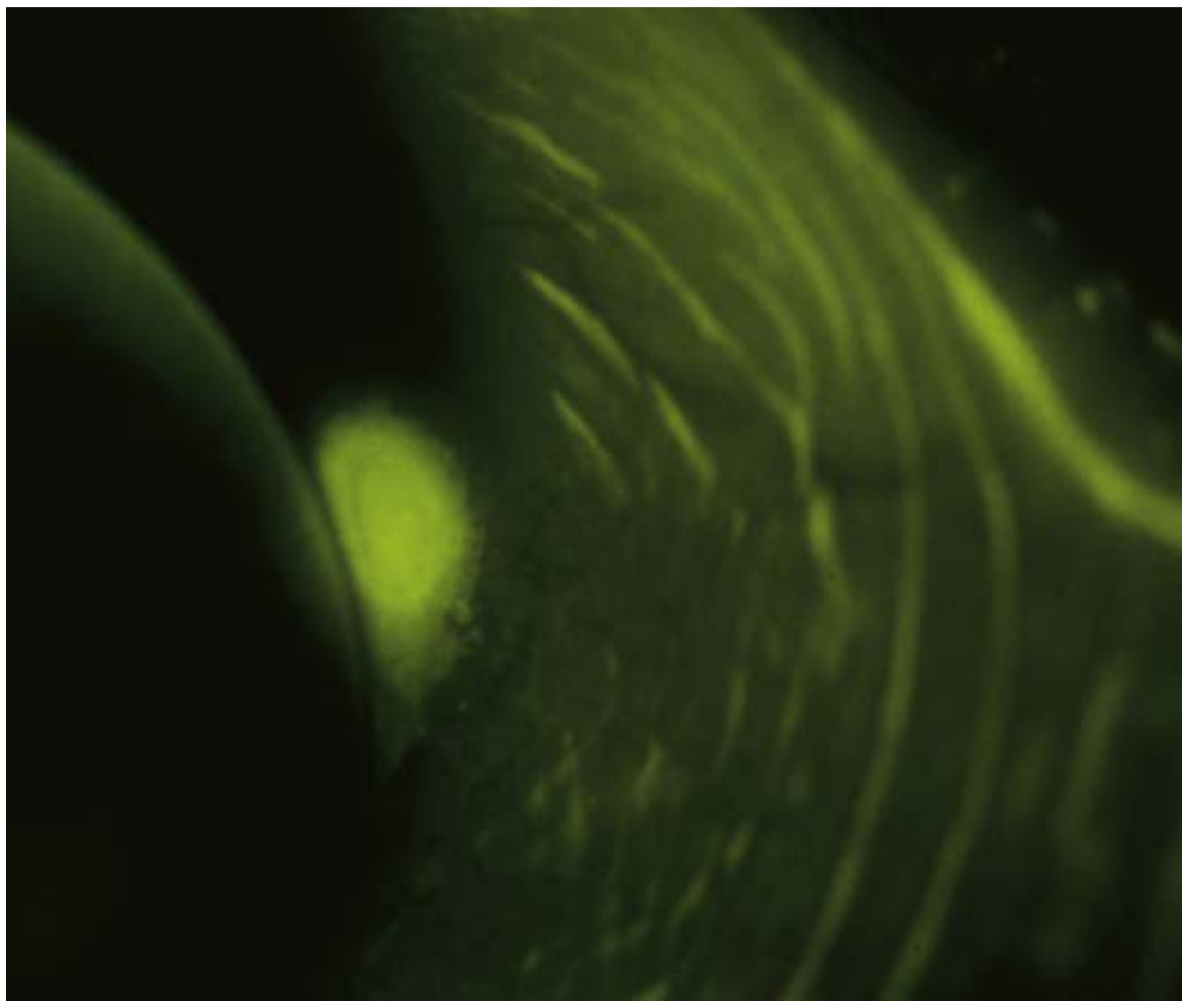

Fig. 40.15 Fluorescein fills natural folds in the conjunctiva. (Courtesy of Bausch & Lomb Slide Library.)

staining and symptoms. They disregarded parallel line patterns, which are attributed to pooling of fluorescein in natural conjunctival folds (Fig. 40.15). It was observed that 98% of all subjects displayed some degree of clinically significant conjunctival staining, but only 12% of the non-wearers versus 62% of the lens wearers exhibited staining greater than grade 1. The symptom of dryness was associated with increased conjunctival staining. Brautaset et al. (2008) reported observing conjunctival staining in 33% of 338 adapted hydrogel contact lens wearers.

An imprint can be created on the conjunctiva as a result of chafing or physical compression by the edge of a soft lens. Chafing may be due to a lens edge design that causes the edge to 'dig in' to the conjunctiva. Defects in the lens edge have also been demonstrated to cause increased conjunctival staining (Efron and Veys, 1992). Fitting a lens with a different edge design and a 'defect-free' edge will alleviate this problem.

Compression staining will usually be accompanied by a tight-fitting and / or a decentred lens. This manifests as a broad ring of heavy conjunctival staining corresponding to the lens edge, which is clearly evident following lens removal (Fig. 40.16). Conjunctival vessels distal to the lens edge may be engorged. The patient is usually asymptomatic. This condition can be solved by refitting the patient with a lens of greater back optic zone radius.

Instillation of fluorescein in a dry-eye patient may reveal the presence of desiccation staining on the conjunctiva, which manifests as a series of diffuse punctate lesions within the interpalpebral zone. The condition will return to normal soon after removing the lens, but long-term resolution may require a combination of treating the underlying cause of the dry eye and refitting the patient with lenses that will facilitate complete conjunctival wetting.

A conjunctival epithelial flap may be seen in patients wearing silicone hydrogel contact lenses. These arcuate formations on the conjunctiva are composed of sheets of cells detached from the underlying conjunctiva, which probably form as a result of physical irritation by the edge of lenses of higher modulus (Graham et al., 2009). They are seen more often in patients wearing lenses on an extended-wear basis (Santodomingo-Rubido et al., 2008). These flaps are asymptomatic, and their clinical significance is unclear.

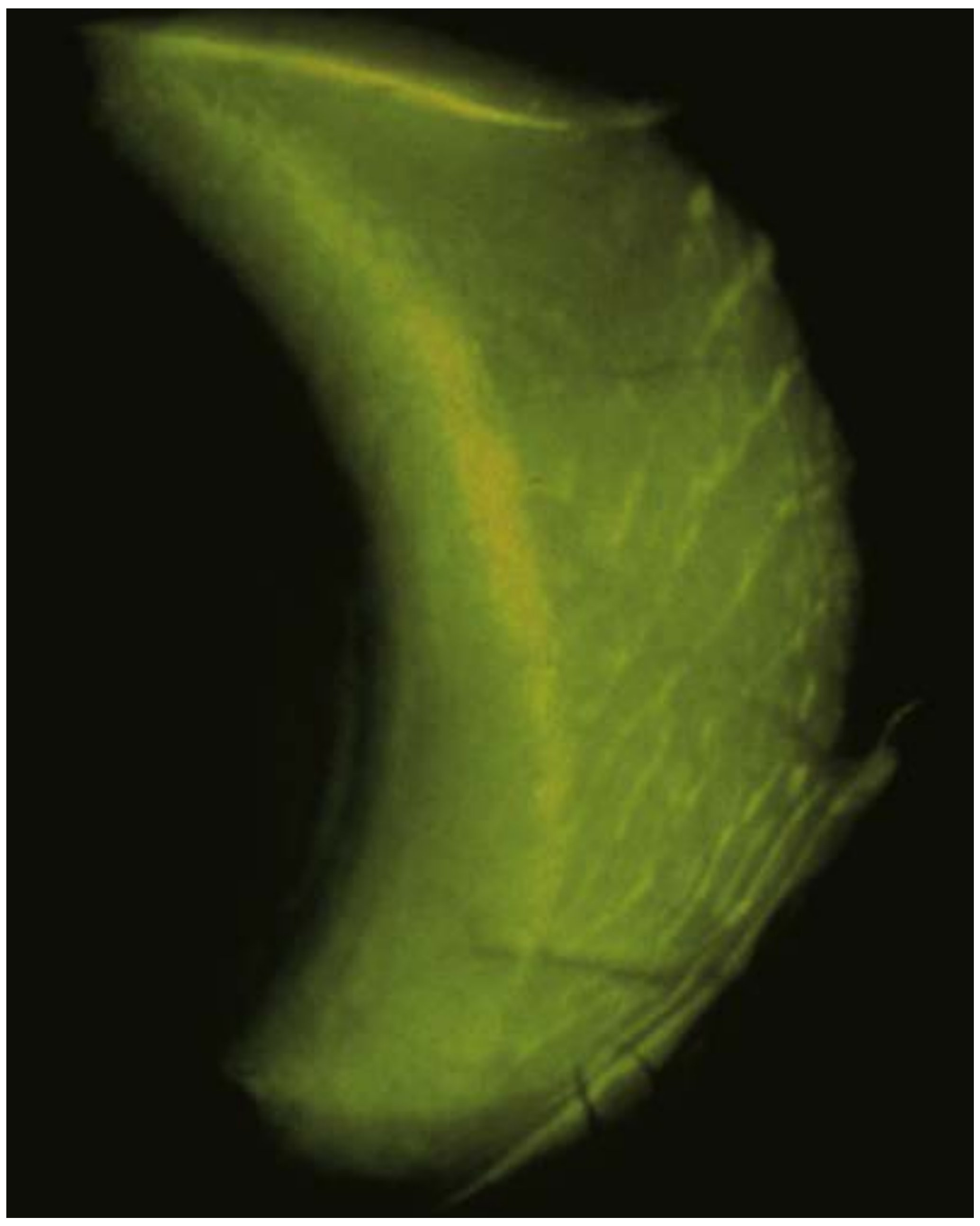

Fig. 40.16 Conjunctival staining caused by compression from the edge of a tight-fitting soft lens. (Courtesy of Marc Robboy, Bausch & Lomb Slide Library.)

Compromise to the conjunctiva as revealed by fluorescein staining is of concern because of recent demonstrations of morphological changes to the conjunctival epithelium associated with lens wear. These changes include alterations to conjunctival cell shape, nuclear morphology and chromatin condensation (Knop and Bremitt, 1992), and they are reported to be more prevalent in symptomatic lens wearers (Aragona et al., 1998). Soft lens wear is also associated with a reduction in goblet cell density (Knop and Bremitt, 1992; Colorado et al., 2016); this could lead to reduced mucin production, which in turn could explain and perhaps further exacerbate pre-existing symptoms of dryness.

CONJUNCTIVAL REDNESS

The clinical presentation of a 'red eye' can be one of the most difficult cases to solve owing to the numerous possible causes that are known. This problem may be even more complex in a contact lens wearer because of the wide variety of causes of red eye. Conjunctival redness in lens wearers is generally asymptomatic, but patients may complain of itchiness, congestion, non-specific mild irritation or a warm or cold feeling (Fig. 40.17). The existence of pain usually indicates corneal involvement or other tissue pathology (e.g. uveitis or scleritis).

The amount of conjunctival redness induced by contact lenses is less with silicone hydrogel lenses than with conventional hydrogel lenses. In a 4-week study of patients who had not worn lenses previously, Maldonado-Codina et al. (2004) observed that conventional hydrogel lenses caused an increase in conjunctival redness of about 0.3 grading scale units (Efron scale), whereas silicone hydrogel lenses induced no change in redness.

The conjunctiva has a rich plexus of arterioles, which contain a thick layer of smooth muscle that is richly enervated with

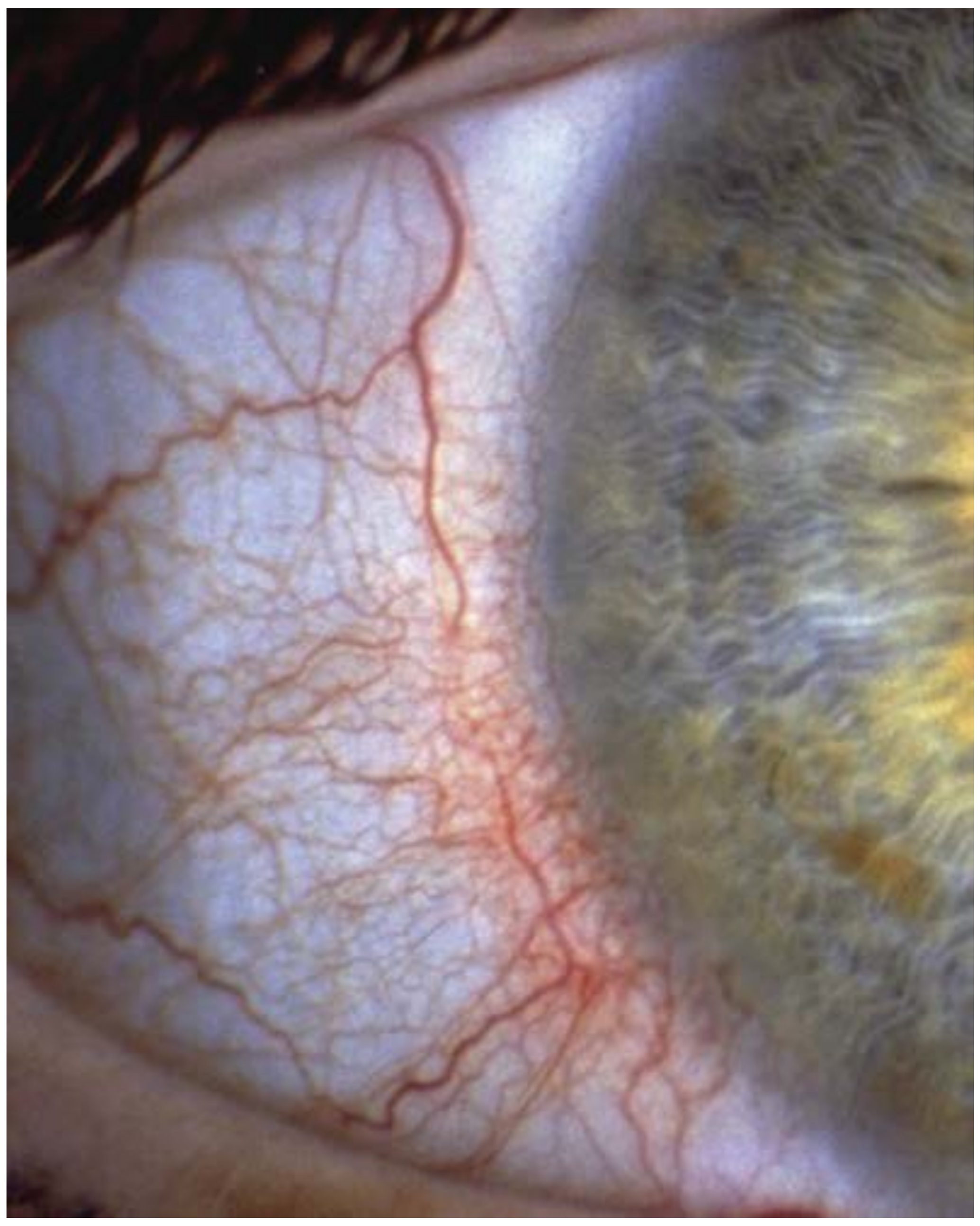

Fig. 40.17 Bulbar conjunctival hyperaemia.

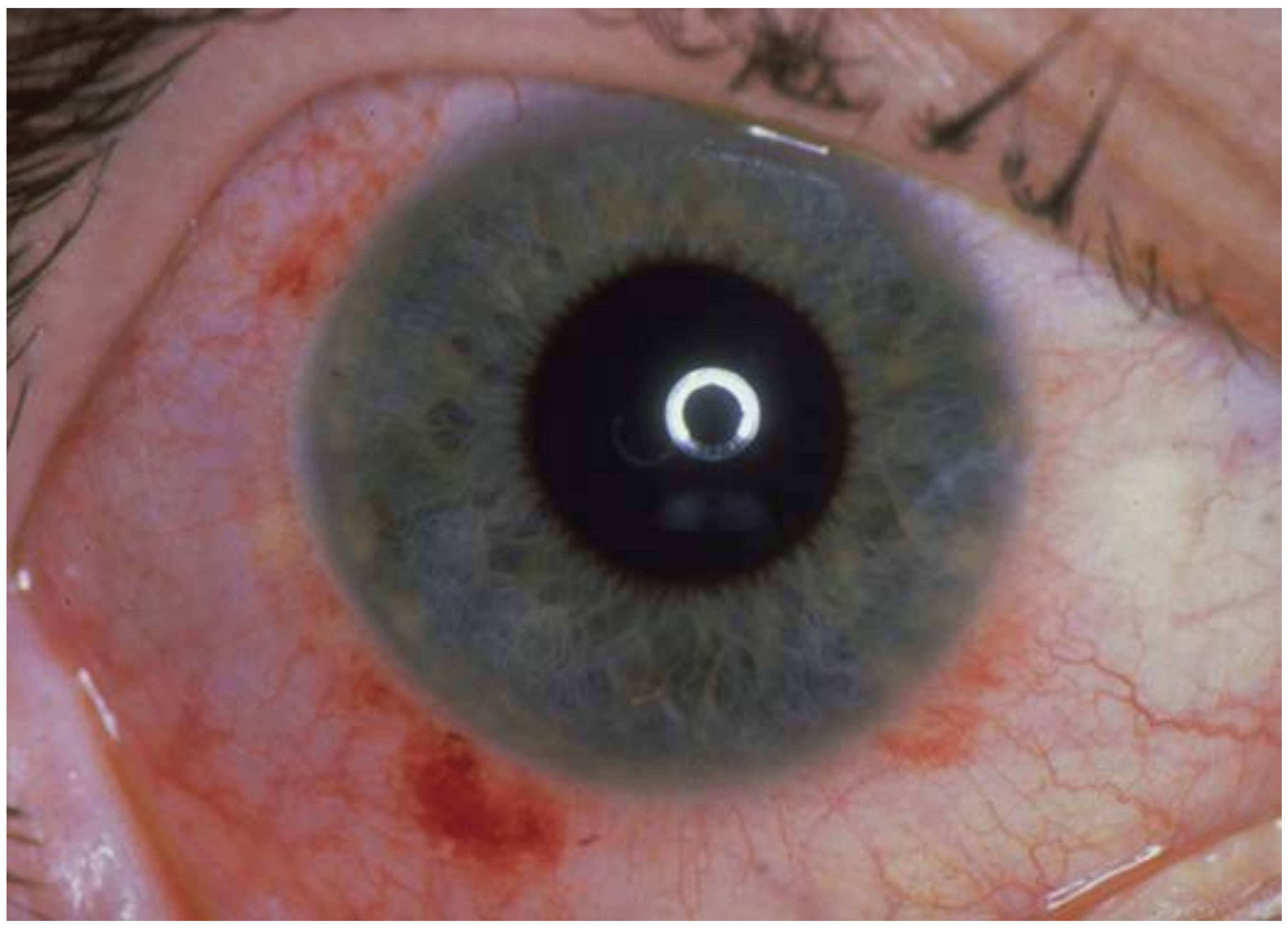

Fig. 40.18 General bulbar conjunctival redness, limbal redness and inferior limbal haemorrhages. Adverse reaction to an experimental disinfecting solution in a 22-year-old female soft lens wearer. (Courtesy of Charline Gauthier, Bausch & Lomb Slide Library.)

sympathetic nerve fibres. The smooth muscle, as well as being under central autonomic control, can be influenced by numerous local changes. Vasodilation refers to enlargement in the circumference of a vessel due to relaxation of its smooth-muscle layer, which leads to decreased resistance and increased blood flow through the vessel (active hyperaemia). As blood vessels can be observed directly through the transparent conjunctiva, this leads to an appearance of increased redness (less white sclera is visible).

A contact lens can have a local mechanical effect on the conjunctiva, resulting in increased redness. As a device that can interfere with normal metabolic processes of the cornea and conjunctiva, and is used in association with various solutions, a contact lens can affect the level of conjunctival redness via a local chemical or toxic effect (Fig. 40.18).

Local infection and inflammation can cause eye redness. Accordingly, treatment options fall into four broad categories:

1. alterations to the type, design and modality of lens wear
2. alterations to care systems
3. improving ocular hygiene
4. prescription of pharmaceutical agents.

The prognosis for recovery from chronic contact-lens-induced redness after removal of lenses and cessation of wear is good. Holden et al. (1986) found that, following approximately 5 years of extended hydrogel lens wear, general conjunctival redness resolved within 2 days. In general, removal of any noxious stimulus, including a contact lens, will lead to a very rapid recovery of eye redness to normal levels.

PAPILLARY CONJUNCTIVITIS

This condition refers to the appearance of localized swellings, or papillae, on the tarsal conjunctiva. Papillae are primarily observed in the upper eyelid, and can be viewed only by everting the lid. Rarely, papillae can be observed on the lower tarsus by pulling the lower lid firmly down. In soft lens wearers, papillae are more numerous; they are located more towards the upper tarsal plate (i.e. closer to the fold of the everted lid), and the apex of the papillae takes on a more rounded form (Fig. 40.19). In rigid lens wearers, papillae are flatter and are located more towards the lash margin, with few papillae being present on the upper tarsal plate. Papillae often appear as round light reflexes, giving an irregular specular reflection (Allansmith et al., 1977).

In the early stages (less than grade 2) of contact-lens-induced papillary conjunctivitis (CLPC), the tarsal conjunctiva may be indistinguishable from the normal tarsal conjunctiva apart from increased redness. In advanced cases (greater than grade 2), papillae can exceed 1 mm in diameter and often take on a bright-red / orange hue. The distribution of papillae can be more readily appreciated with the aid of fluorescein (Fig. 40.20). The hexagonal / pentagonal shape is lost in favour of a more rounded appearance, with a flattened or even slightly depressed apex or tip. A tuft of convoluted capillary vessels is often observed at the apex of papillae; this vascular tuft will typically stain with fluorescein. Other signs in severe CLPC (greater than grade 3) include conjunctival oedema, excessive mucus and mild ptosis. The cornea may display punctate staining and superior infiltrates. Injection of the superior limbus may also be apparent.

Skotnitsky et al. (2006) have proposed that two distinct clinical presentations of CLPC are observed in hydrogel lens wearers: local and general. This classification is based on location and extent of papillae, whereby CLPC is classified as local if papillae are present in one to two areas of the tarsal conjunctiva and general if papillae occur in three or more areas. CLPC is less commonly associated with silicone hydrogel lens wear (Sorbara et al., 2009).

There is general concordance between the severity of signs and symptoms. In the early stages of CLPC, patients may complain of discomfort towards the end of the wearing period, slight itching, excess mucus upon awakening, intermittent blurring or a slight but non-variable vision loss while wearing lenses. As the condition progresses, patients report itching, discomfort and excessive lens movement.

Key factors implicated in the aetiology of CLPC include lens-induced mechanical irritation, and immediate and delayed hypersensitivity. There is often a link with meibomian gland dysfunction, and atopic patients may be more susceptible to developing the condition.

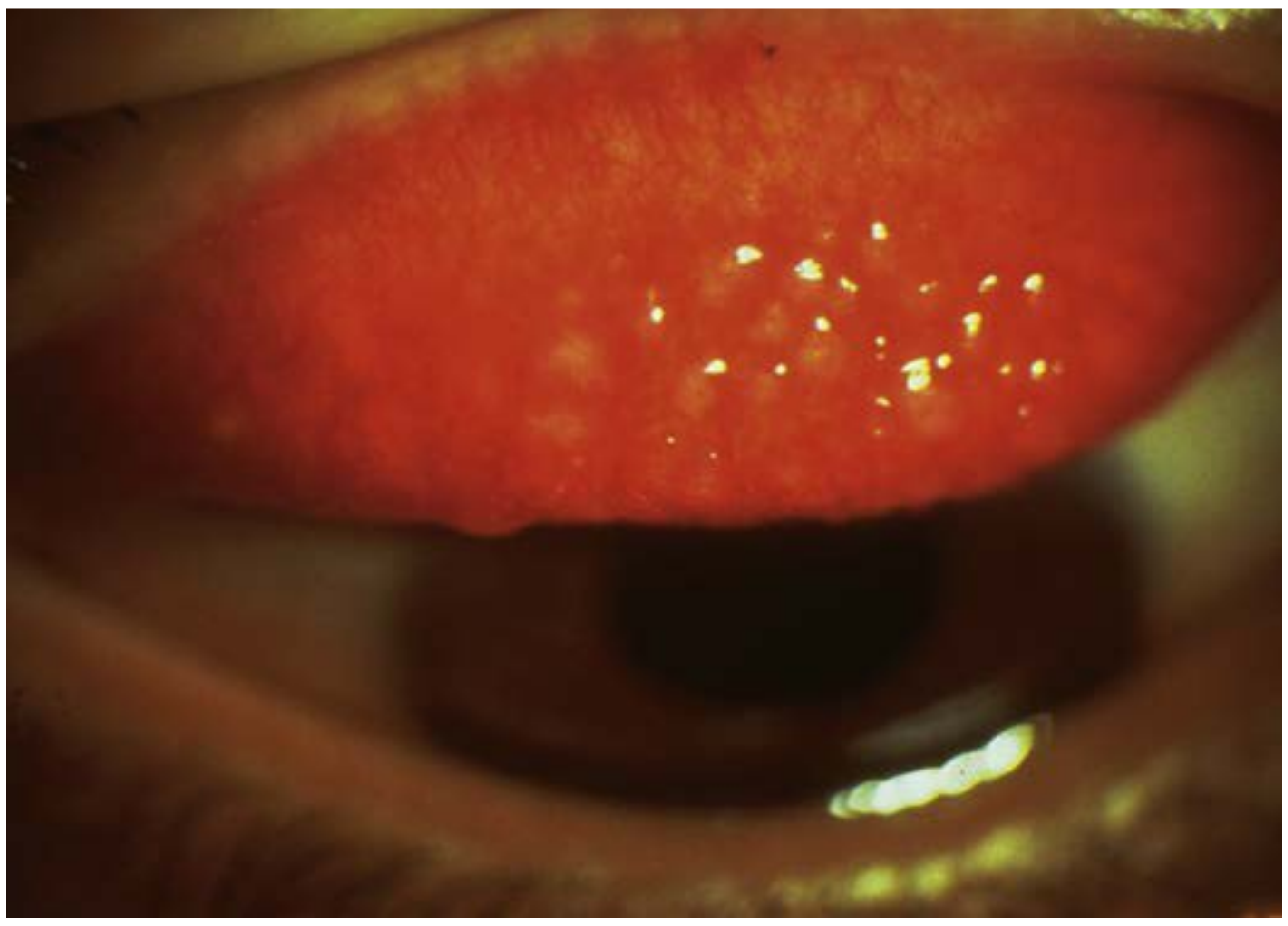

Fig. 40.19 Everted eyelid revealing the presence of contact-lens-induced papillary conjunctivitis. (Courtesy of C. D. Euwijk, Bausch & Lomb Slide Library.)

Treatment options include:

- altering the lens material
- replacing lenses more frequently (Porazinski and Donshik, 1999)
- altering or eliminating the care system
- improving ocular hygiene
- treating any associated meibomian gland dysfunction
- prescribing pharmaceutical agents such as soft steroids (e.g. loteprednol etabonate), mast cell stabilizers (e.g. 4% cromolyn sodium), combined antihistamine/mast cell stabilizers (e.g. olopatadine hydrochloride 0.1% or ketotifen fumarate 0.025%)
- dispensing ocular lubricants for symptomatic relief
- reducing wearing time
- suspending or ceasing lens wear.

Compared with planned-replacement hydrogel lenses, daily disposable hydrogel lenses reduce the risk of papillary conjunctivitis by 50% (Radford et al., 2009).

The prognosis for recovery from CLPC after removal of lenses and cessation of wear is good, with symptoms disappearing within 5 days to 2 weeks of lens removal, and redness and excess mucus resolving over a similar time course. Resolution of papillae takes place over a much longer time course – typically many weeks and as long as 6 months. The more severe the condition, the longer is the recovery period. In the longer term, however, the prognosis is less good. The condition can recur, especially in atopic patients who appear to have a propensity for developing CLPC.

Limbus

The limbus is of particular significance in contact lens wear because it is a complex anatomical entity by way of it being a transition zone between the cornea and conjunctiva, and it is the region of the anterior eye that is often in close proximity to the edge of both rigid and soft lenses.

LIMBAL REDNESS

Assuming that a given case of eye redness is lens related, it is necessary to determine whether the source of the problem is the cornea or conjunctiva. Conjunctival redness associated with a quiet limbus and absence of pain indicates a primary conjunctival problem. Conjunctival redness associated with an injected limbus and corneal pain indicates more corneal involvement, or indeed a problem that is related exclusively to the cornea. Careful slit-lamp examination of the anterior ocular structures, and inspection of the contact lens at high magnification, will generally reveal the cause of the problem. It may also be necessary to prescribe different care systems and differentially diagnose the effects of various solutions over time.

In the absence of any clinically observable ocular pathology, corneal hypoxia is the likely cause of excessive limbal redness (Fig. 40.21). Hypoxia stimulates the release of inflammatory mediators from the limbal vessel walls leading to vasodilatation; this is an automatic reaction designed to facilitate a greater flow of oxygenated blood to the distressed tissue. This mechanism fails in the case of the limbus because limbal blood flow contributes little to corneal oxygenation; the cornea derives virtually all

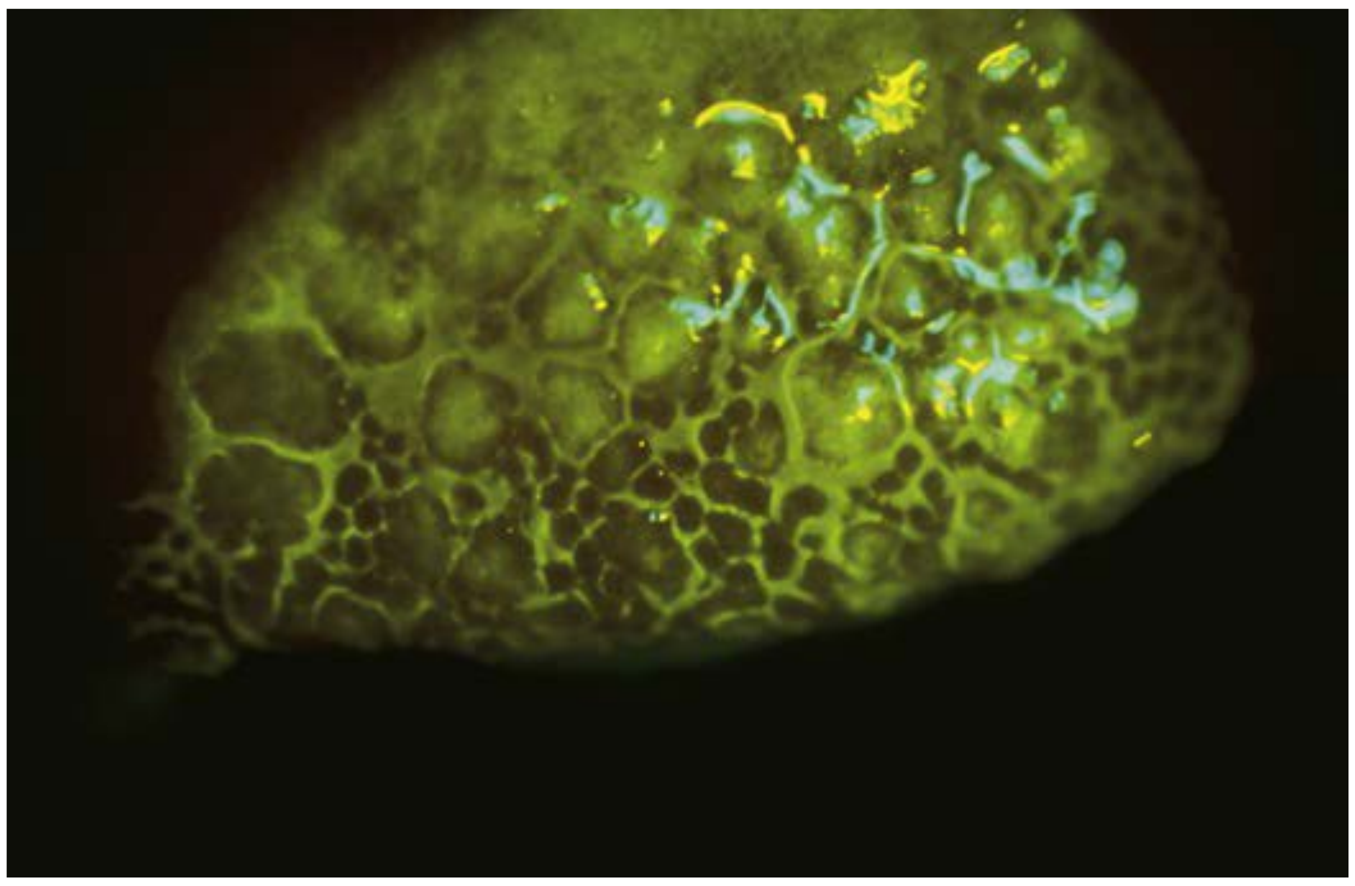

Fig. 40.20 Distribution of papillae as revealed by fluorescein (same eye as in Fig. 40.19). (Courtesy of C. D. Euwijk, Bausch & Lomb Slide Library.)

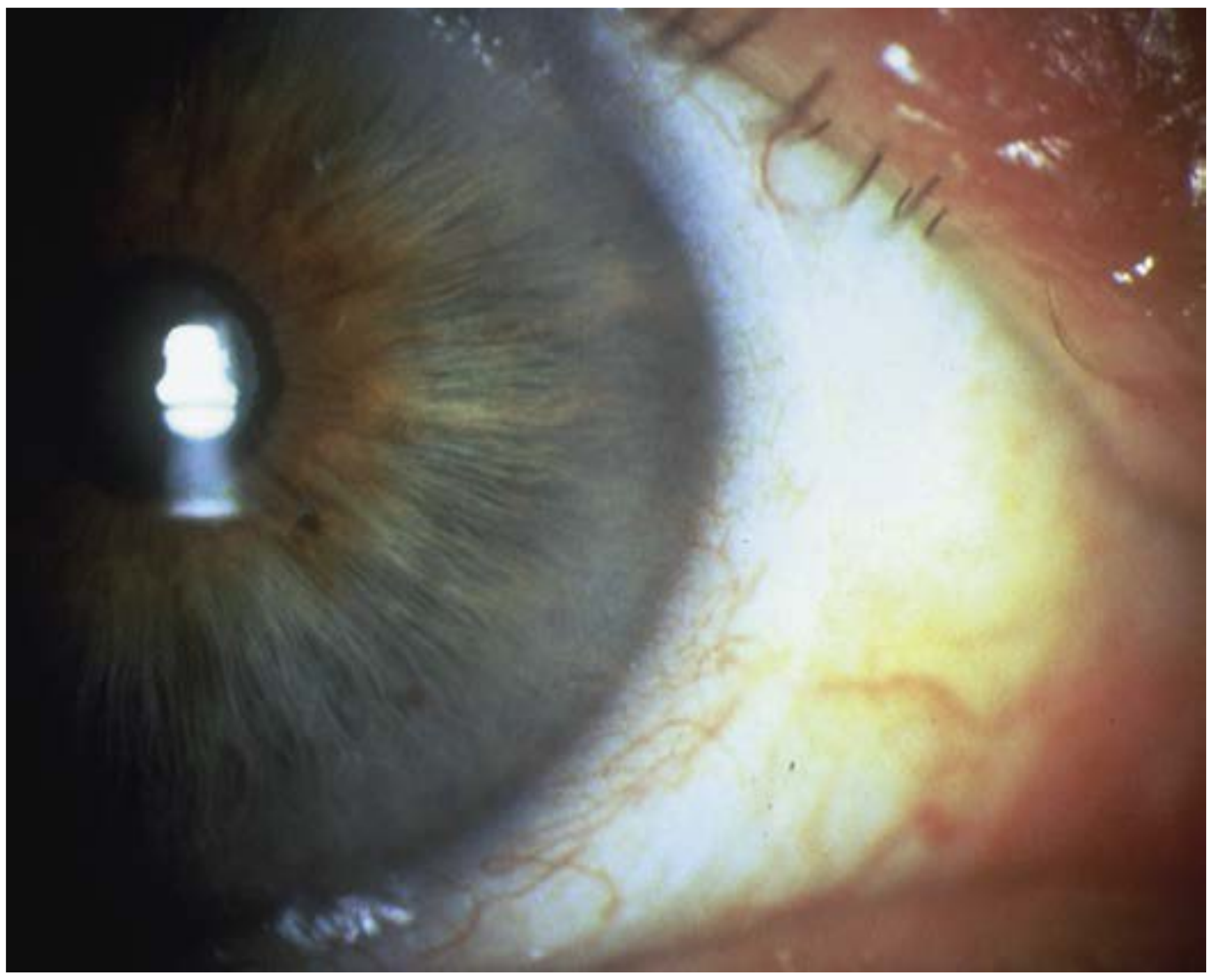

Fig. 40.21 Circumlimbal redness due to hypoxia induced by a soft lens of low oxygen transmissibility. (Courtesy of Bausch & Lomb Slide Library.)

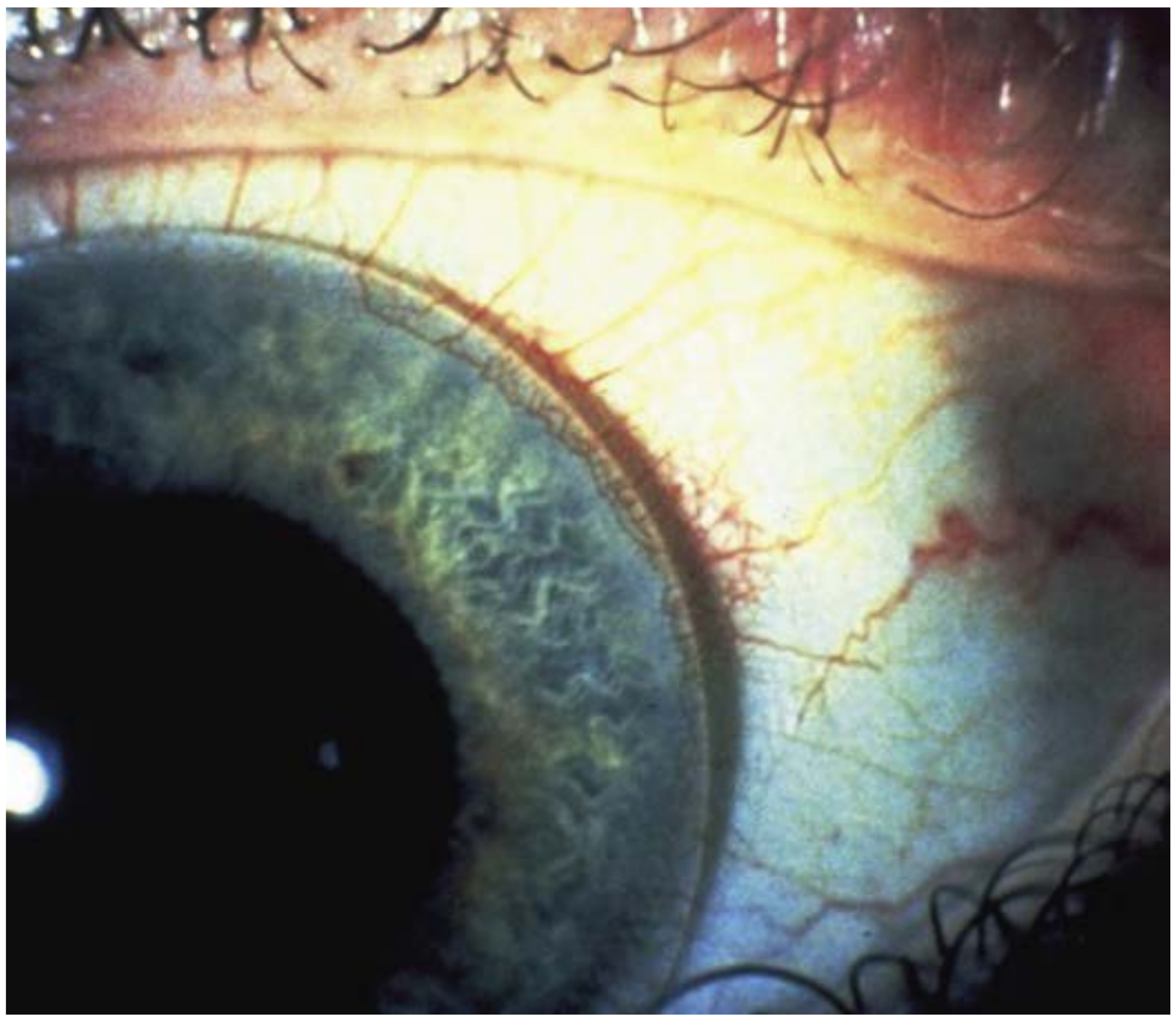

Fig. 40.22 Limbal redness due to direct physical irritation from the thick edge of a soft lens that is of insufficent diameter for this patient. (Courtesy of Bausch & Lomb Slide Library.)

of its oxygen supply from the atmosphere. The result, therefore, is contact-lens-induced hypoxia maintaining chronic limbal vessel engorgement in a vain attempt to reoxygenate the cornea.

Papas (1998) has demonstrated a significant relationship between the oxygen transmissibility of the peripheral region of the lens and limbal redness. Indeed, one of the key benefits of high-permeability silicone hydrogel lenses is that they induce very low levels of limbal redness (Maldonado-Codina et al., 2004).

Although hypoxia is presumed to be the key determinant of limbal redness, practitioners should be alert to the possibility of other causes, such as poor lens edge design (Fig. 40.22) or pathology of the anterior ocular structures, especially the cornea.

The prognosis for recovery from chronic contact-lens-induced limbal redness after removal of lenses and cessation of wear is good. Holden et al. (1986) found that, following approximately 5 years of extended lens wear, general conjunctival redness resolved within 2 days, whereas recovery from limbal redness had a longer time course, taking about 7 days to resolve.

VASCULARIZED LIMBAL KERATITIS

This condition is observed in patients wearing rigid contact lenses on an extended-wear basis. It manifests as a limbal inflammation – typically at either the 3 or 9 o'clock positions – and an encroachment of limbal vessels (Fig. 40.23). The adjacent conjunctiva may be oedematous and hyperaemic, and the lesion may be surrounded by fine superficial punctate epithelial staining and mild corneal infiltration (Fig. 40.24) (Grohe and Lebow, 1989). The patient may be only mildly symptomatic, complaining of ocular dryness. The problem may be exacerbated if the lens surface is crazed or deposited (Miller, 1995).

This condition often occurs in regions of the limbus that have become desiccated owing to poor wetting of the ocular surface. This problem is caused by bridging of the lids away from the globe, thus preventing the lids from distributing tears over the affected area. In this regard, vascularized limbal keratitis may be an advanced form of 3 and 9 o'clock staining. In late stages of this condition, the lesion can become slightly raised, in the form of a thickened mass of epithelial tissue through which blood vessels traverse at various depths (Fig. 40.25) (Grohe and Lebow, 1989). This epithelial hypertrophy may be related to the fact that the limbus contains a high concentration of stem cells, creating a greater capacity for epithelial cell mitosis and movement. Also, the limbus hosts a vast array of immunological mechanisms mediated via the reticuloendothelial system in limbal vessels.

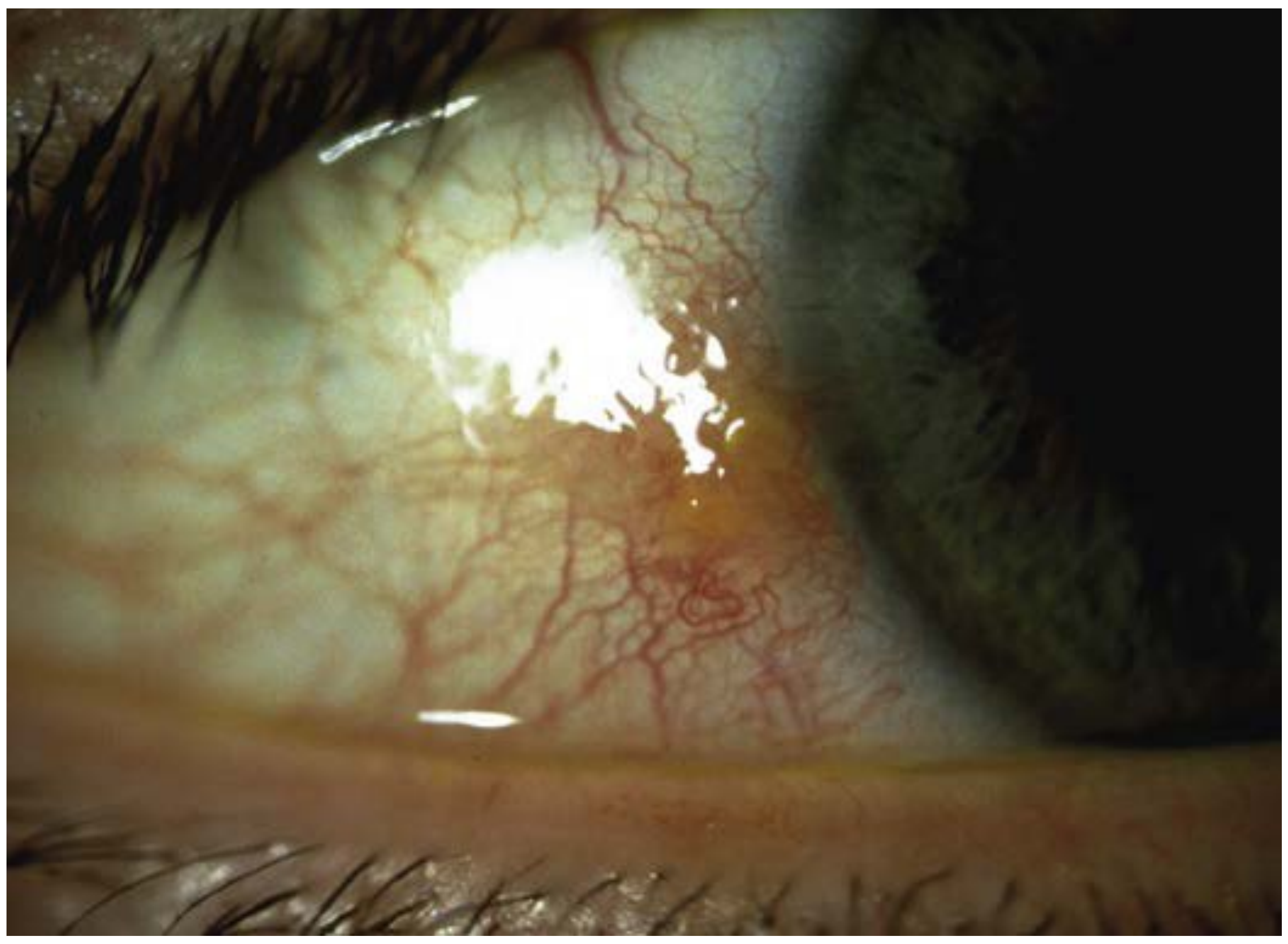

Fig. 40.23 Vascularized limbal keratitis in a rigid lens wearer. (Courtesy of Debbie Jones, Bausch & Lomb Slide Library.)

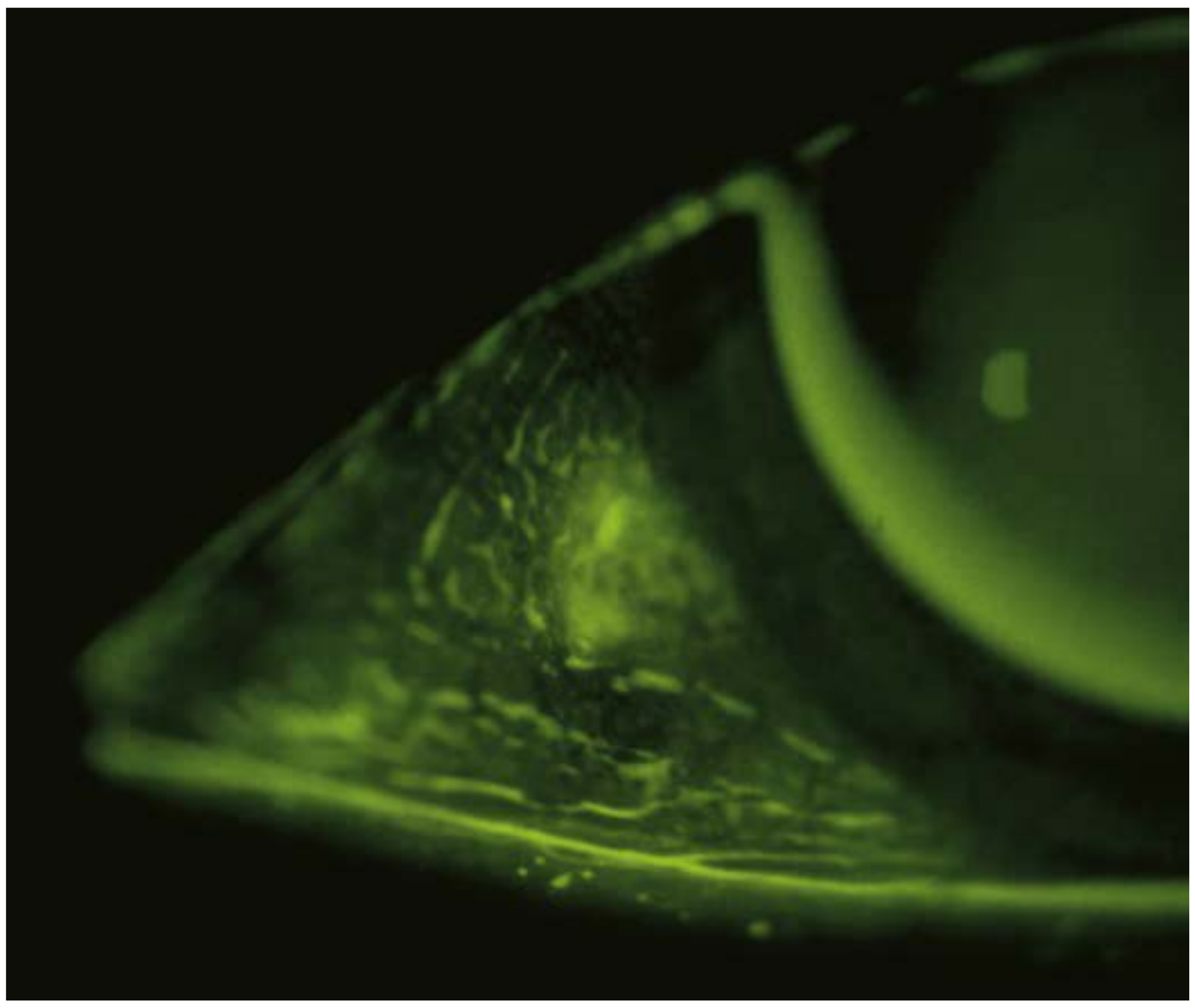

Fig. 40.24 Epithelial mass in vascularized limbal keratitis staining with fuorescein (same patient as in Fig. 40.23). (Courtesy of Debbie Jones, Bausch & Lomb Slide Library.)

Vascularized limbal keratitis is reversible, and cessation of lens wear for a few weeks will allow most of the pathology to resolve. Converting the patient from extended wear to daily wear, and refitting with a smaller-diameter lens, may prevent the problem from recurring. Changing from rigid to soft lenses will certainly eliminate the problem.

SUPERIOR LIMBIC KERATOCONJUNCTIVITIS

In its mild form, contact-lens-induced superior limbic keratoconjunctivitis (CLSLK) is easy to overlook. The condition is

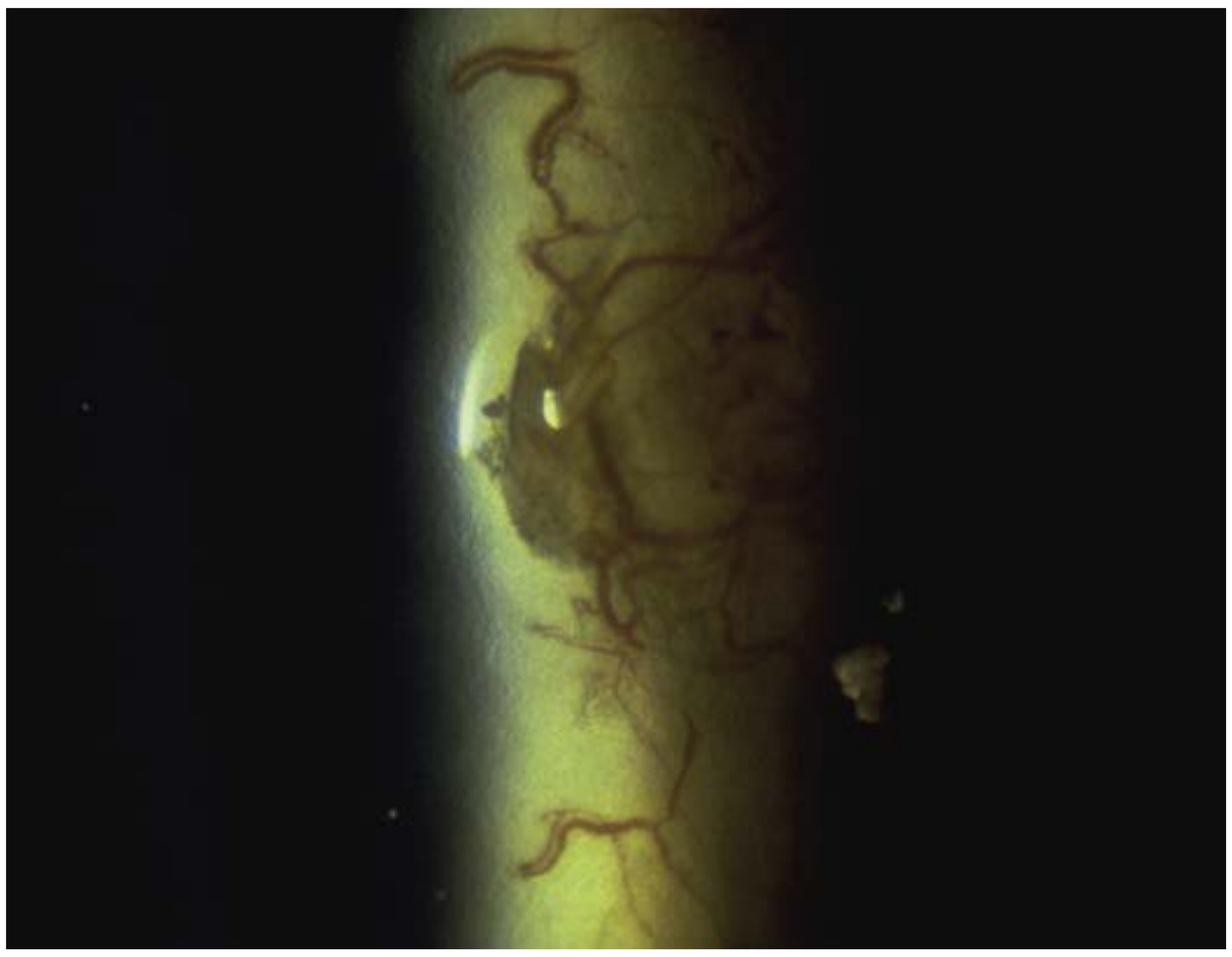

Fig. 40.25 High-magnification view (×40) of epithelial mass in vascularized limbal keratitis. (Courtesy of Robert Terry, Bausch & Lomb Slide Library.)

confined to the superior limbal area and as such is hidden by the upper lid in primary gaze. The proper procedure for observing this condition is to lift the upper lid while the patient gazes down.

A myriad of signs are observed in the region of the superior limbus in patients with CLSLK; these include:

- punctate epithelial fluorescein staining
- epithelial rose bengal staining
- intraepithelial opacities
- subepithelial haze
- epithelial dulling
- microcysts
- infiltrates and irregularities
- stromal fibrovascular micropannus
- fine subepithelial linear opacities
- limbal oedema
- hypertrophy
- fluorescein staining
- vascular injection
- poor wetting
- punctate staining
- hyperaemia
- chemosis
- irregular thickening of the superior bulbar conjunctiva
- papillary and follicular hypertrophy
- hyperaemia and petechiae of the upper tarsal conjunctiva
- corneal filaments
- corneal warpage and astigmatism
- corneal pseudodendrites (Fig. 40.26) (Stenson, 1983).

The tissue compromise progresses from the limbus to the centre of the cornea in a V-shaped pattern with the apex directed towards the pupil centre (Fig. 40.27).

Symptoms of CLSLK include increased lens awareness, lens intolerance, foreign-body sensation, burning, itching, photophobia, redness, increased lacrimation, slight mucus secretion and slight loss of vision. This condition is uncommon, and occurs mostly in soft lens wearers. It is almost always bilateral, and the specific signs often display symmetry between the eyes. There is considerable variability in the time course of onset of the condition; signs usually becomes manifest between 2 months and 2 years after commencement of lens wear.

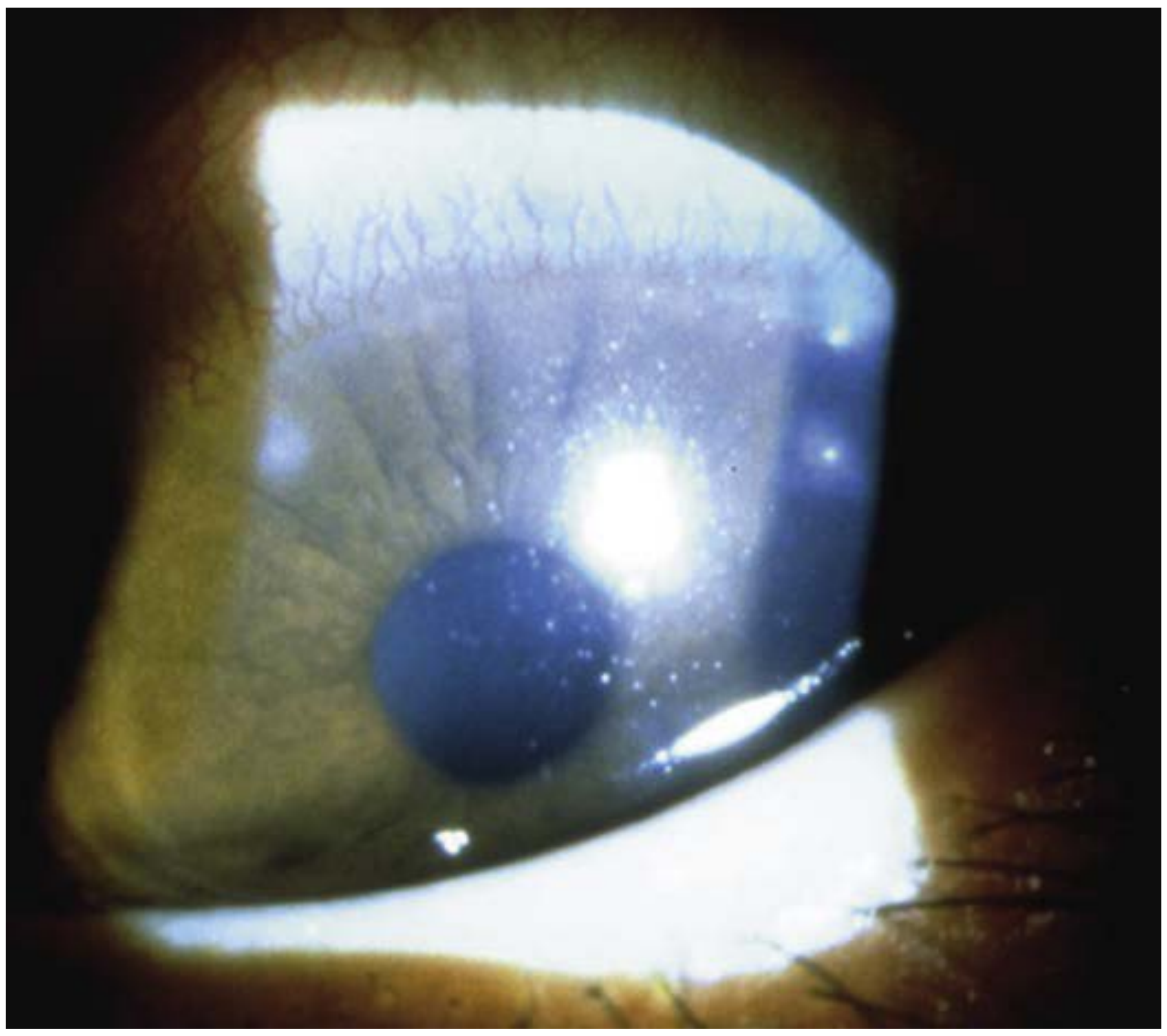

Fig. 40.26 Early stage of superior limbic keratoconjunctivitis (grade 1.0) showing superior limbal hyperaemia, focal infiltrates, increased lacrimation (indicated by full lacrimal river) and epithelial decompensation (indicated by hazy slit-lamp reflex).

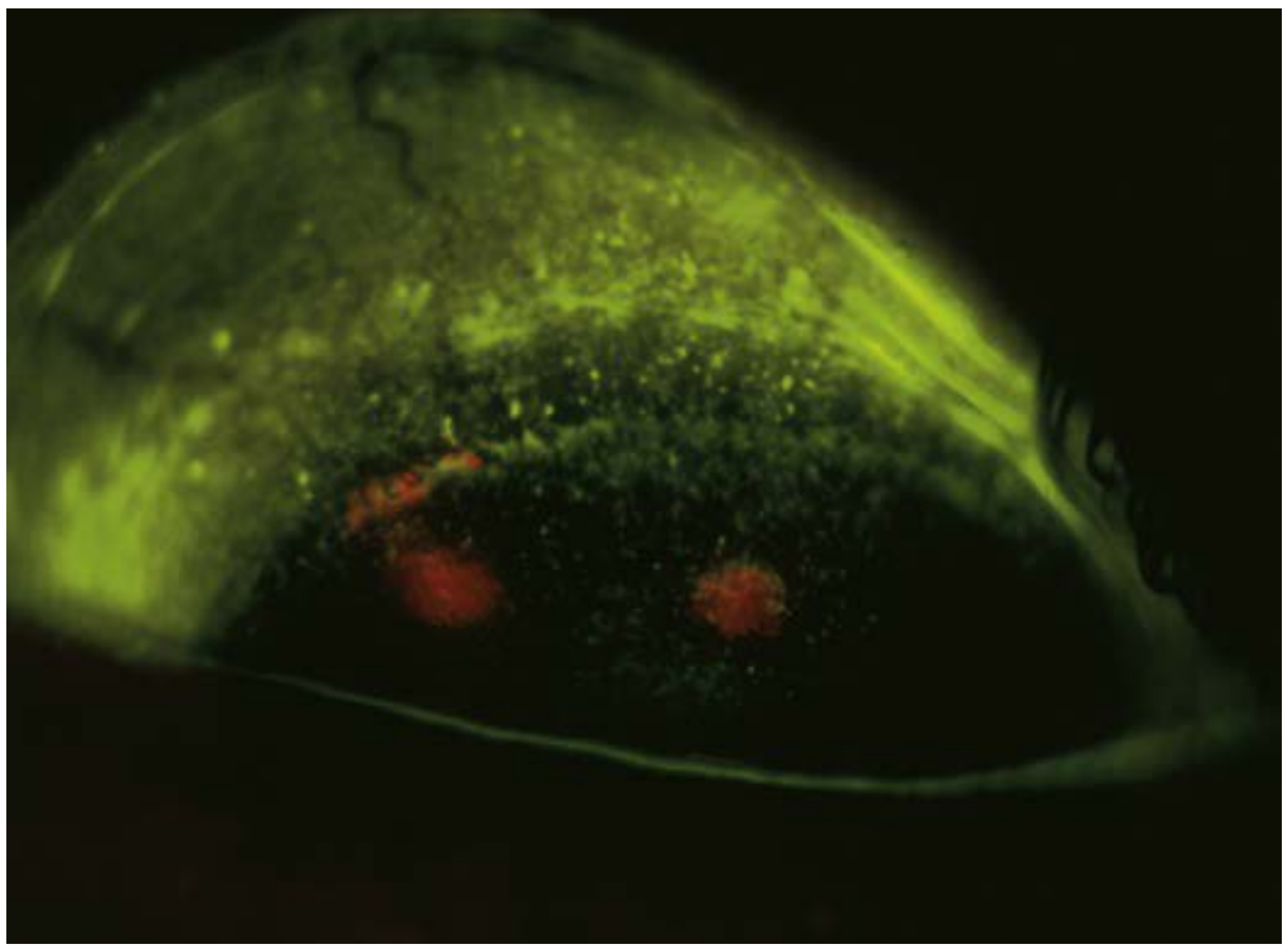

Fig. 40.27 Fluorescein reveals tissue compromise in superior limbic keratoconjunctivitis (grade 2.3). (Courtesy of Mee Sing Chong, Bausch & Lomb Slide Library.)

The primary aetiological factor in the development of CLSLK is thimerosal hypersensitivity (Wilson et al., 1981) – a preservative that is no longer used in contact lens care solutions. Provocative tests in thimerosal-sensitized patients result in general circumlimbal redness (not just confined to the superior limbus), meaning that contact lens wear must be having an impact on the clinical presentation of CLSLK, which is confined to the superior limbus. Although other factors perhaps play a minor role by initiating, modulating or exacerbating the condition, it is unlikely that CLSLK will develop in the absence of ocular contact with thimerosal. Other factors implicated in the aetiology of CLSLK include thimerosal toxicity, mechanical effects, lens deposits and hypoxia beneath the upper lid.

Patients suffering from CLSLK may be advised to cease lens wear for 2–4 weeks if less than grade 2 and up to 3 months in severe cases (greater than grade 2). All previously worn lenses should be discarded. Refitting can be undertaken when the corneal haze has largely resolved and the corneal surface is smooth (less than grade 1); however, a vascular pannus may be permanent. Lens wear can be resumed in the presence of a vascular pannus as long as the patient is monitored closely to check for the absence of further vascular encroachment. Thimerosal and any other potentially allergenic preservatives should be excluded from the care system. Single-use daily disposable lenses are the best option. Ocular lubricants in the form of drops or ointments may provide symptomatic relief during the recovery phase, further to a positive placebo effect in a naturally anxious patient. Clinical signs and visual acuity will resolve within about 4 months of cessation of lens wear, although this can vary between 3 weeks and 9 months.

Corneal Epithelium

The corneal epithelium is in direct contact with a contact lens, and is thus susceptible to physical trauma. Being highly metabolically active, the epithelium is also sensitive to metabolic insult. In the case of contact lens wear, the primary metabolic insult is an interference with normal tissue respiration. Many of the complications that are observed throughout the full depth of the cornea are mediated by the epithelium.

EPITHELIAL STAINING

Epithelial staining is not strictly a condition in itself – rather, it is a general term that refers to the appearance of tissue disruption and other pathophysiological changes in the anterior eye, as revealed with the aid of one or more of a number of dyes, such as fluorescein, rose bengal, lissamine green, fluorexon or alcian blue (Efron, 2013). Fluorescein has by far the greatest utility in contact lens practice, so the terms 'epithelial staining' and 'corneal staining' are taken to mean staining with fluorescein, unless stated otherwise.

Epithelial staining following instillation of fluorescein is observed under cobalt blue light as a bright green fluorescence, which can be described as 'punctate' (spot-like) (Fig. 40.28), 'diffuse' (spots merging together) and 'coalescent' (large regions of confluence). The staining pattern may be described according to the following groups of type descriptors: arcuate, linear or dimpled; superior, inferior, temporal, nasal or central; and deep or superficial (Korb and Korb, 1970). Staining 'syndromes' include inferior epithelial arcuate lesion ('smile stain'), superior epithelial arcuate lesion (otherwise known as 'epithelial splitting') and exposure keratitis. An 'epithelial plug' refers to a large coalescent field of full-thickness epithelial loss.

Observed areas of fluorescence are believed to indicate one of three phenomena: (1) fluorescein entering damaged cells, (2) fluorescein entering intercellular spaces, or (3) fluorescein filling gaps in the epithelial surface that are created when epithelial cells are displaced (Wilson et al., 1995). However, Morgan and Maldonado-Codina (2009) point out that our clinical understanding and interpretation of corneal surface fluorescence are based upon assumption, extrapolation and clinical intuition rather than solid evidence-based science underpinning the basic causative mechanisms of this phenomenon.

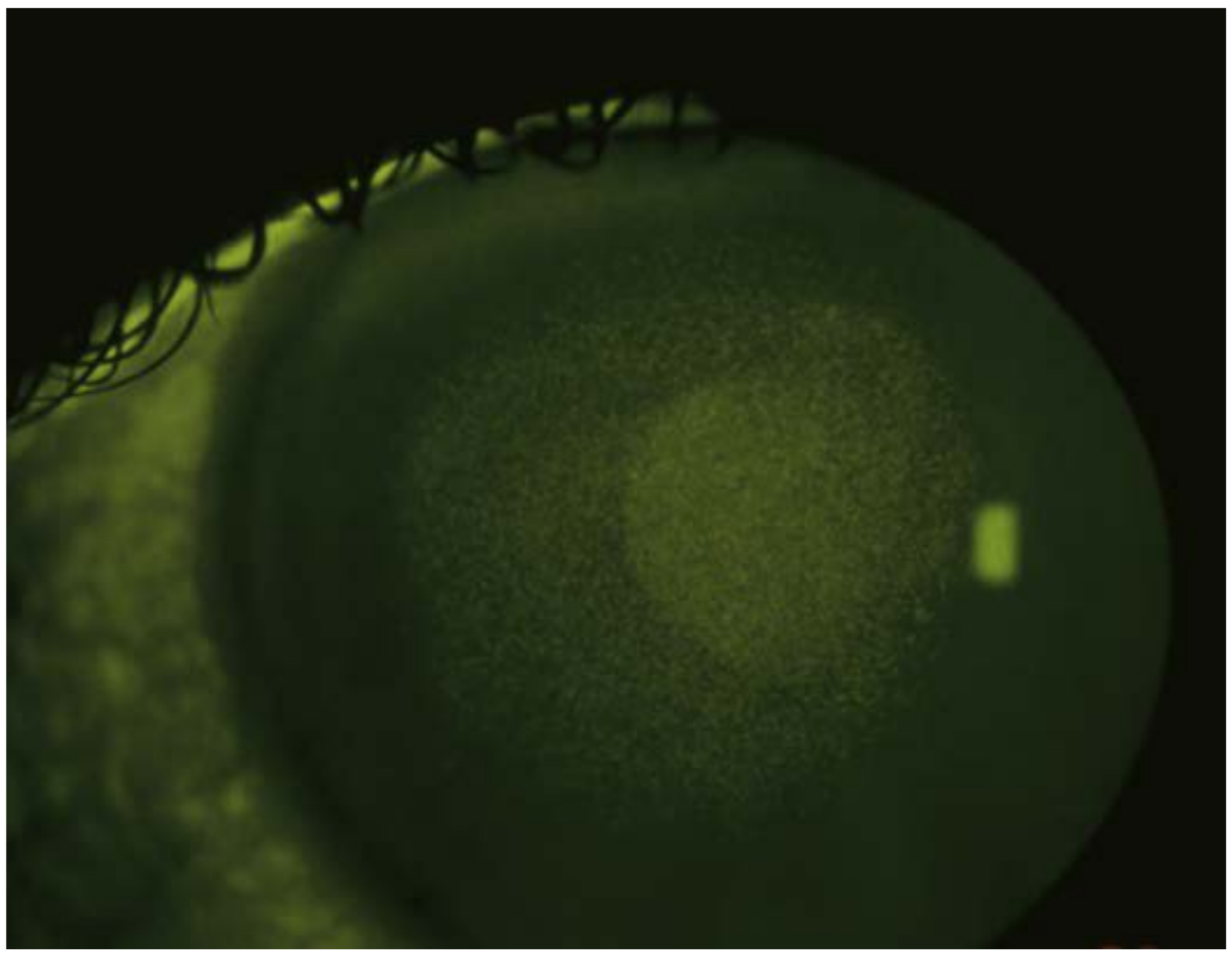

Fig. 40.28 Extensive superficial punctate epithelial staining. (Courtesy of Gary Orsborn, Bausch & Lomb Slide Library.)

Bandamwar et al. (2014) have demonstrated that micropunctate fluorescein staining identifies individual cells that are undergoing apoptosis, whereby the cells have internalized fluorescein and are hyperfluorescent relative to neighbouring cells. Normal, healthy cells also take up fluorescein, but fluoresce less brightly than apoptotic cells. Dead cells do not fluoresce appreciably.

Severe staining (grades 3 and 4) may be accompanied by bulbar conjunctival redness and chemosis, limbal redness, excessive lacrimation and, in some cases, stromal infiltrates, depending on the cause of the problem. Visual acuity is generally unaffected by epithelial staining, although a slight loss might be expected in extreme cases (grade 4). There is no clear relationship between the severity of staining and the degree of ocular discomfort.

There are numerous causes of epithelial staining, which can be broadly classified into six aetiological categories: mechanical, exposure, metabolic, toxic, allergic and infectious. In many cases the pattern of staining, and whether the condition presents in one or both eyes, can provide a clue to the cause. Low-level staining (less than grade 2) does not necessarily require action to be taken. Such staining is commonly observed in contact lens wearers; it is typically transient and in a daily lens wearer will have disappeared by the following morning. However, persistent minor staining forming a characteristic pattern, as well as staining greater than grade 2, may require intervention.

Management strategies are generally self-evident if the cause can be discerned. For example, mechanical trauma due to a foreign body trapped beneath a rigid lens (Fig. 40.29) can be resolved by removing and rinsing the lens and rinsing the eye; exposure keratitis causing 3 and 9 o'clock staining in a rigid lens wearer can be resolved by fitting soft lenses; epitheliopathy due to metabolic disturbance can be solved by fitting a lens of higher oxygen transmissibility; staining due to toxicity or allergy can be resolved by eliminating the toxic or allergic agent; staining associated with an infection is treated by applying the appropriate antimicrobial therapy. Recovery from epithelial staining generally occurs within hours or days of removal of the offending source, but will be more prolonged if lenses are worn during the recovery period.

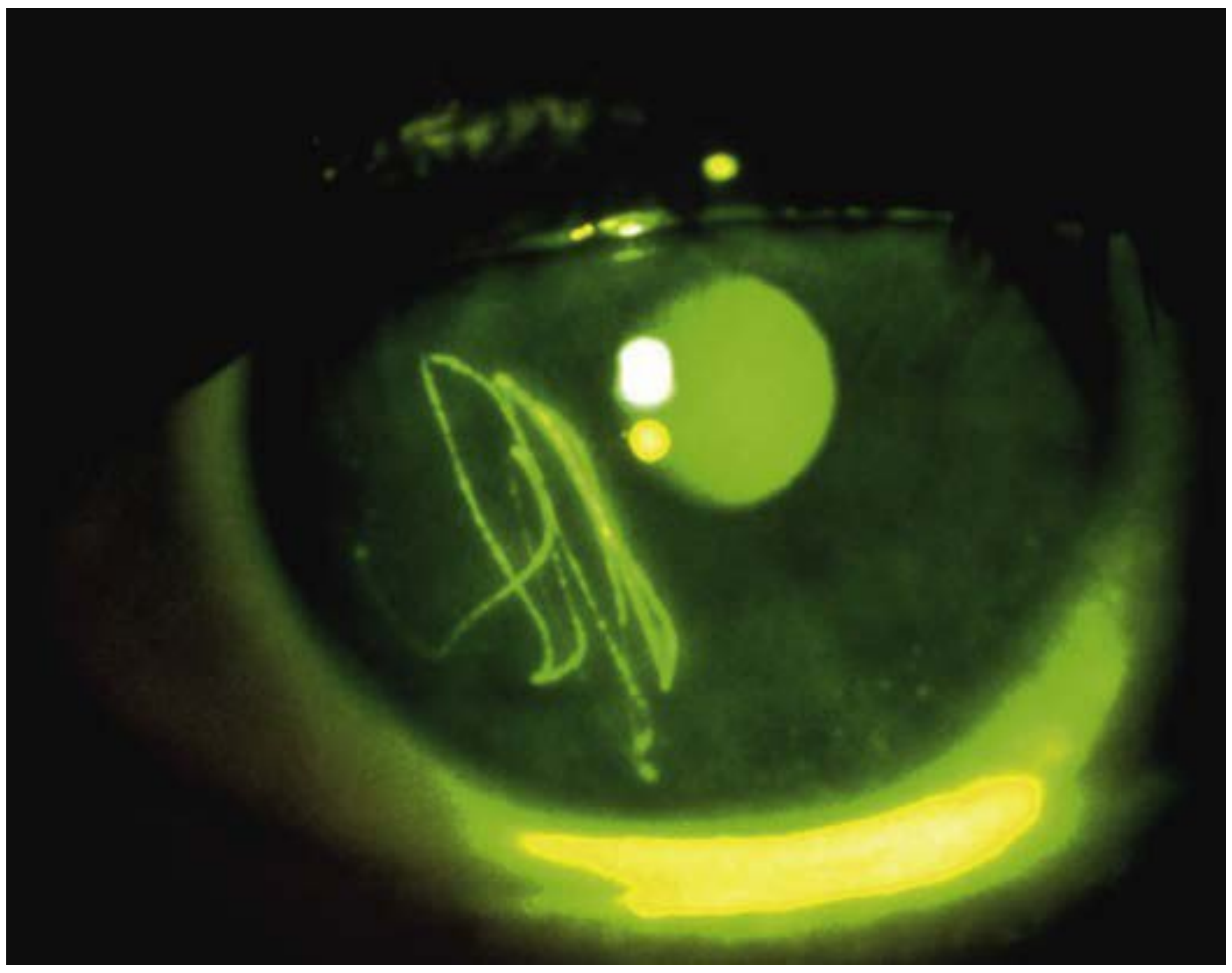

Fig. 40.29 Foreign-body track stain in a rigid lens wearer revealed with the aid of fluorescein. (Courtesy of Debbie Jones, Bausch & Lomb Slide Library.)

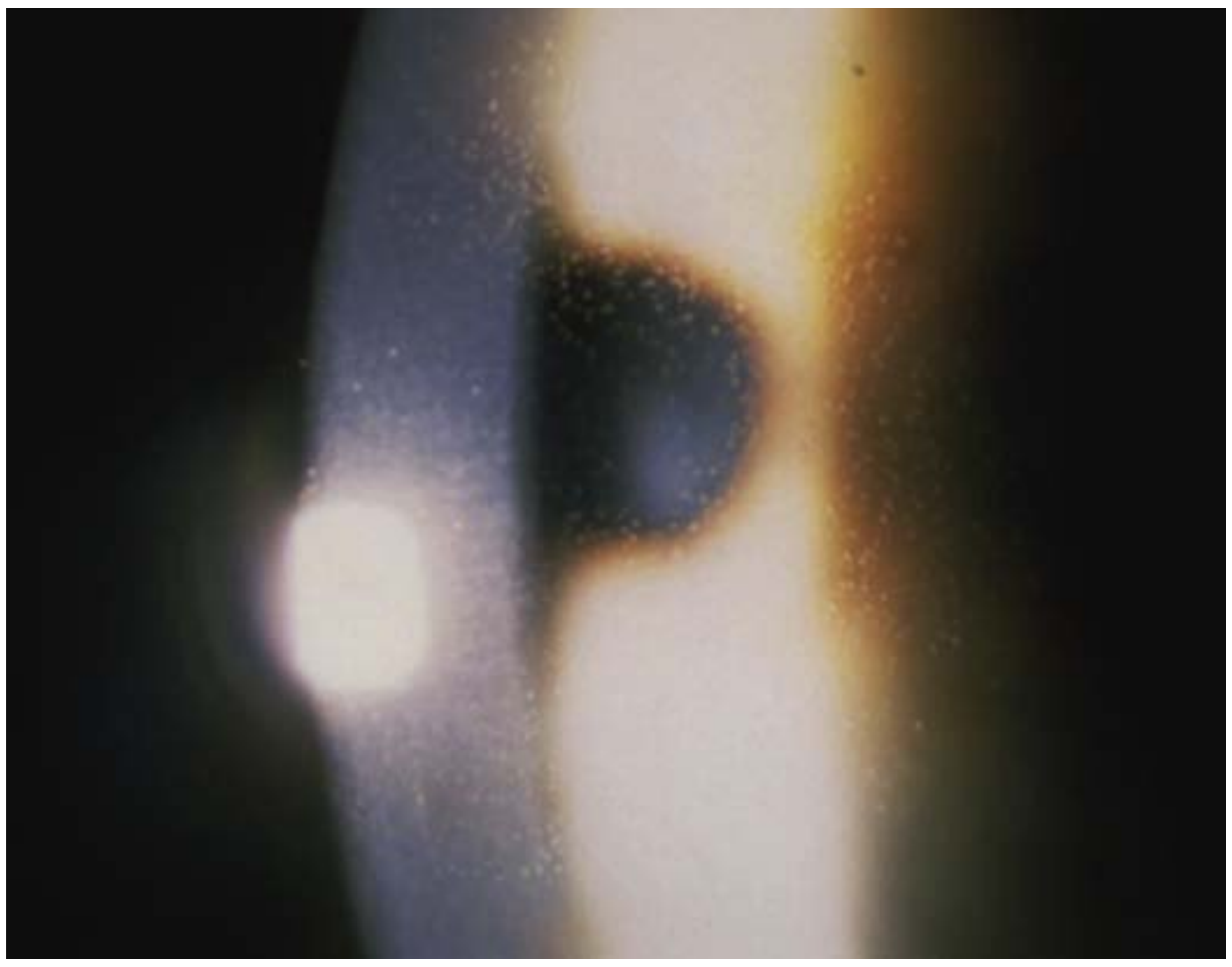

Fig. 40.30 Extensive formation of epithelial microcysts in a soft lens wearer.

MICROCYSTS

Microcysts appear as minute scattered grey opaque dots when viewed with the slit-lamp biomicroscope using low magnification and focal illumination (Fig. 40.30), and as transparent refractile inclusions with indirect retroillumination. They are generally of a uniform spherical or ovoid shape and are in the order of 20 µm in diameter. At high magnification (×40) using the observation technique of marginal retroillumination, microcysts can be observed to display a characteristic optical phenomenon known as 'reversed illumination' – that is, the distribution of light within the microcyst is opposite to the light distribution of the background (Fig. 40.31). This indicates that the microcyst is acting as a converging refractor; therefore, it must consist of material that is of a higher refractive index than the surrounding epithelium. Microcysts probably represent apoptotic (dead) cells that either become phagocytosed (ingested) by living neighbouring cells, or remain involuted in the intercellular spaces. In a process similar to that occurring in Cogan's microcystic dystrophy, the epithelial basement membrane reduplicates and folds, forming intraepithelial sheets that eventually detach from the basement membrane and encapsulate the cellular debris (Holden and Sweeney, 1991).

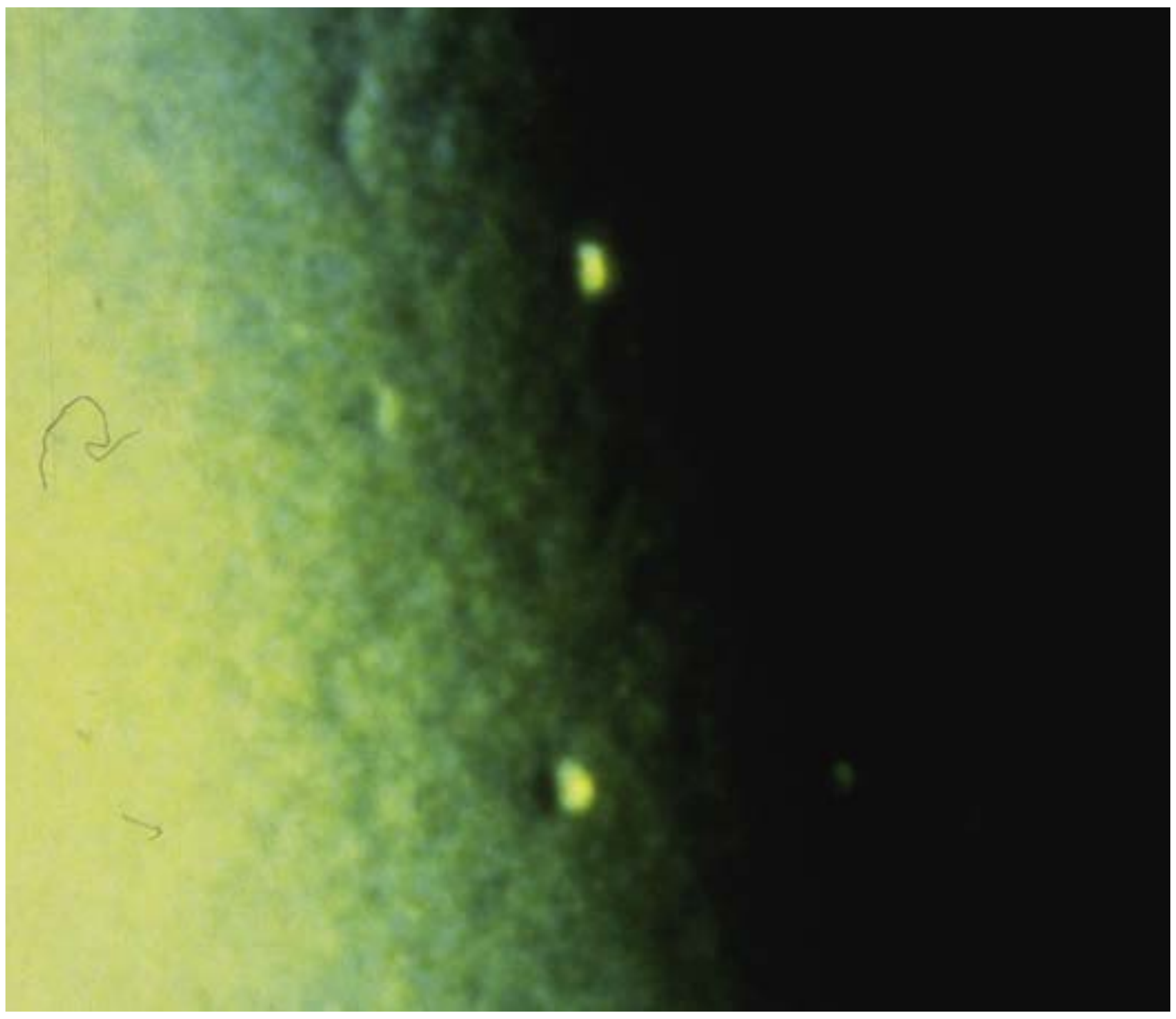

Fig. 40.31 High-magnification image (×200) of two epithelial microcysts, displaying reversed illumination. (Courtesy of Steve Zantos.)

Microcysts primarily represent visible evidence of chronic tissue metabolic stress and altered cellular growth patterns. These changes are presumed to be caused by a combination of the direct effects of hypoxia, and tissue acidosis created by the indirect effects of hypoxia (producing lactic acid) and hypercapnia (producing carbonic acid). They may also have a mechanical aetiology; Efron and Veys (1992) provided evidence that lens-induced mechanical trauma can induce microcysts.

Although the presence of microcysts is not thought to be dangerous, their existence in large numbers is worrying as this is representative of epithelial metabolic distress. Based on the working hypothesis that the severity of the microcyst response is related to the level of hypoxia / hypercapnia induced by lens wear, a variety of strategies can be employed in an attempt to minimize the number of microcysts. Strategies that are likely to be successful include refitting with high-oxygen-transmissibility silicone hydrogel lenses (Covey et al., 2001; Keay et al., 2001; Brennan et al., 2007), decreasing the frequency of overnight wear, changing from extended wear to daily wear, changing from soft to rigid lenses and avoiding defective lenses.

The prognosis for eliminating microcysts is good, but the time course is peculiar. Following cessation of lens wear, there is an initial increase over a 7-day period in the number of microcysts, followed by a subsequent decrease. The initial increase in microcysts is thought to be due to an initial resurgence in epithelial metabolism and growth, resulting in an accelerated removal of cellular debris (formation of microcysts) and a rapid movement of microcysts towards the surface, where they become more visible. This is followed by a gradual decrease as the existing microcysts are completely eliminated from the cornea over a period of 3–5 months (Holden et al., 1985a).

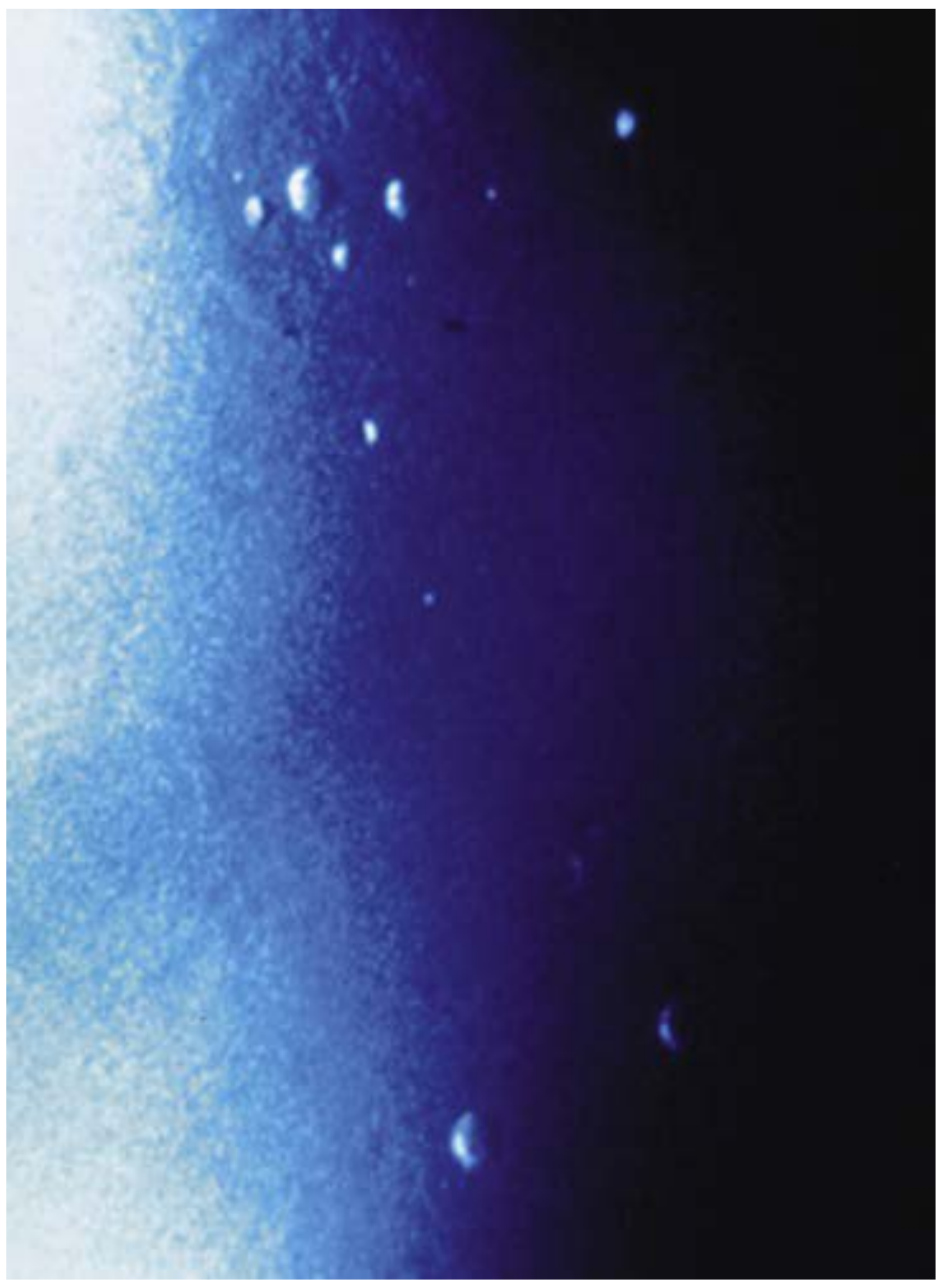

Fig. 40.32 Epithelial vacuoles, displaying unreversed illumination. (Courtesy of Steve Zantos.)

VACUOLES

When the cornea is severely compromised, such as in the case of severe stromal oedema or an extensive microcyst response, the epithelium can also become oedematous; this manifests as the appearance of small fluid vacuoles in the epithelium. By observing the cornea using indirect retroillumination on the slit-lamp biomicroscope, fluid vacuoles can be observed to display 'unreversed illumination' – that is, the distribution of light within the microcyst is the same as the light distribution of the background (Fig. 40.32). This indicates that the microcyst is acting as a diverging refractor; therefore, it must consist of material that is of a lower refractive index (fluid) than the surrounding epithelial tissue (Zantos, 1983).

The aetiology of epithelial fluid vacuoles is twofold. Epithelial oedema follows traumatic loss of surface epithelial cells. The fluid barrier (zonula occludens) that is normally found between surface epithelial cells is breached, resulting in the movement of fluid into the deeper layers of the epithelium. Since the cells are tightly fitted and attach snugly together, the oedema may not occur instantly or be widespread. Epithelial oedema can also form as a result of hypotonic ocular exposure, which can compromise the integrity of the fluid barrier. Animal studies have demonstrated the coexistence of epithelial oedema and thinning following periods of rigid lens wear.

The flare observed with fluorescein in and around corneal abrasions is epithelial oedema. Histopathological evaluation of corneas following hypotonic exposure demonstrates that the oedema is extracellular and is present throughout the full thickness of the epithelium (Krutsinger and Bergmanson, 1985). Reflex tears are of low tonicity and may also provoke epithelial oedema, such as during adaptation to rigid lenses.

Breakdown of the corneal fluid barrier, as indicated by the presence of fluid vacuoles, can lead to secondary problems. For example, contaminated low-tonicity water – such as that which may be found in a hot tub – has an association with contracting an Acanthamoeba keratitis. The amoeba may use the spaces created between cells by the oedematous state to gain entry to the cornea. This scenario is possible in both contact lens wearers and non-lens wearers. Fluid vacuoles can break through the anterior epithelial surface, leading to a very painful condition (Fig. 40.33). Practitioners should therefore take action to eliminate fluid vacuoles from the epithelium by treating the underlying cause, which generally equates to the prescription of highly gas-permeable contact lenses that afford optimal corneal oxygenation.

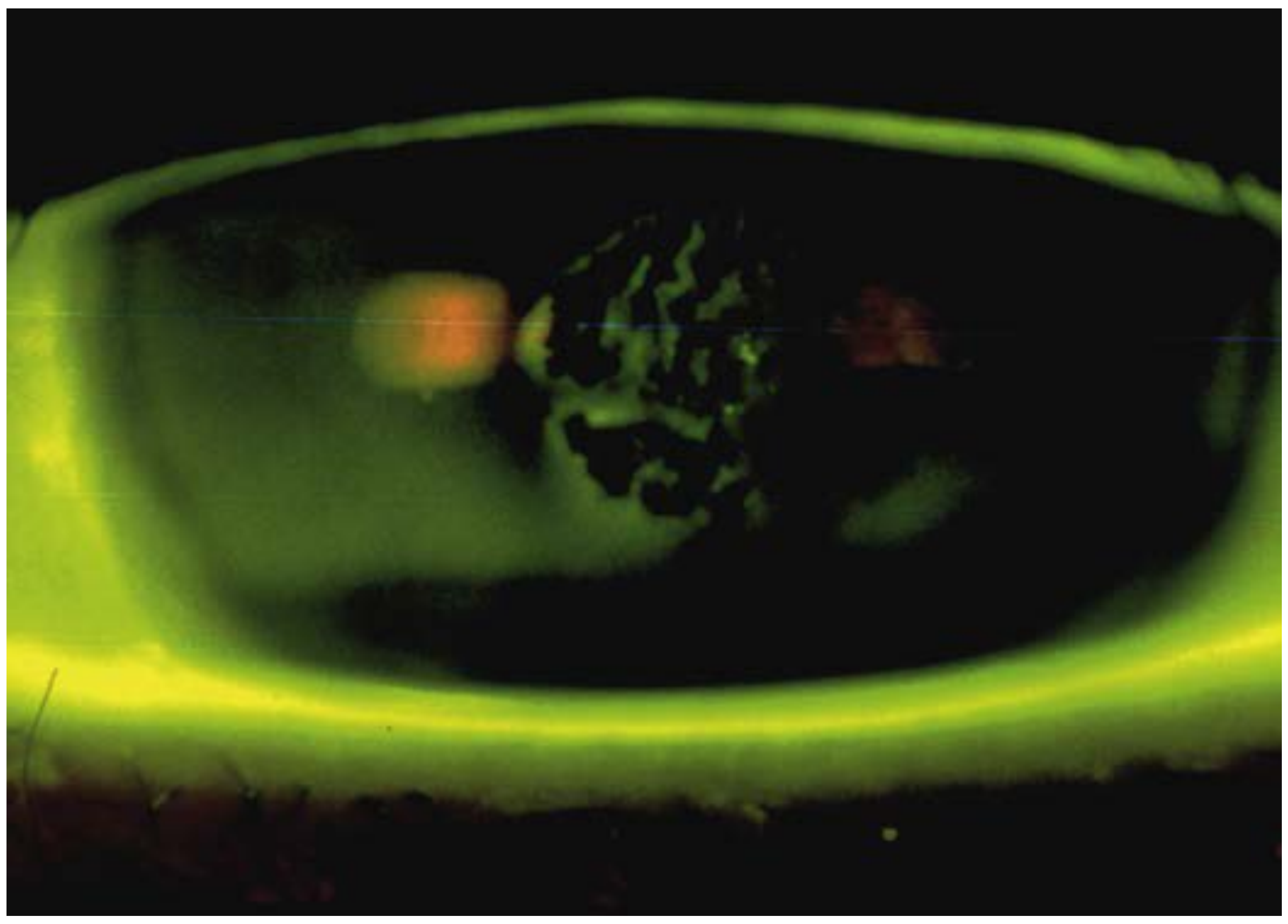

Fig. 40.33 Vacuole eruption through anterior layers. The patient had been wearing high-oxygen-transmissibility rigid lenses on an extended-wear basis for 3 years, and awoke one day with stinging and blurred vision. (Courtesy of Ruth Cornish, Bausch & Lomb Slide Library.)

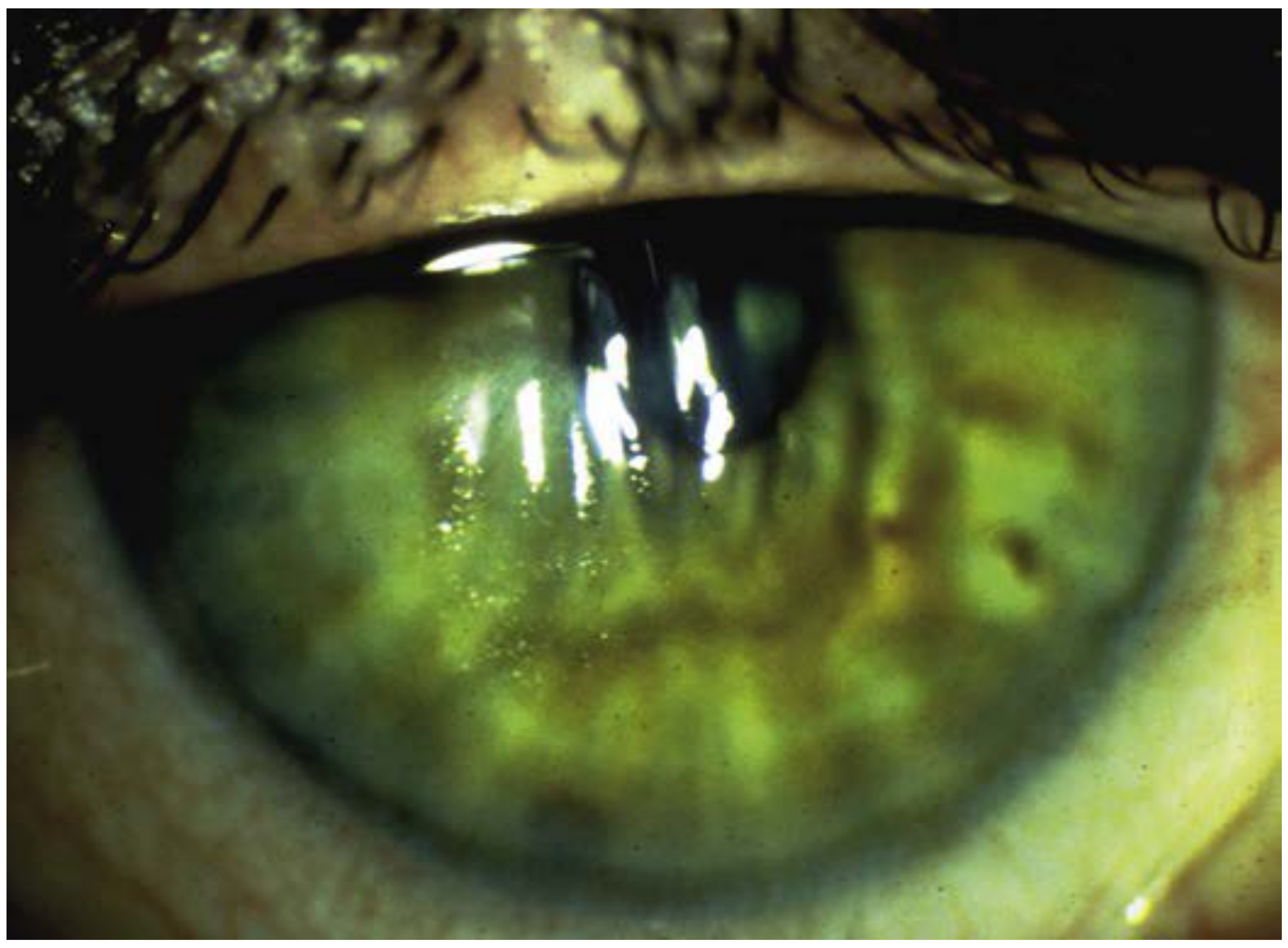

Fig. 40.34 Severe corneal wrinkling. (Courtesy of Brien Holden, Bausch & Lomb Slide Library.)

WRINKLING

Corneal wrinkling is a rare but severe ocular complication of contact lens wear, characterized by the appearance of a series of deep parallel grooves, giving the impression of a 'wrinkled' cornea. In white light, the ridges of the wrinkles can be seen as bright reflexes (Fig. 40.34). The case described by Lowe and Brennan (1987) took the form of two linear wave patterns of fluorescein pooling across the cornea and intersecting at an angle

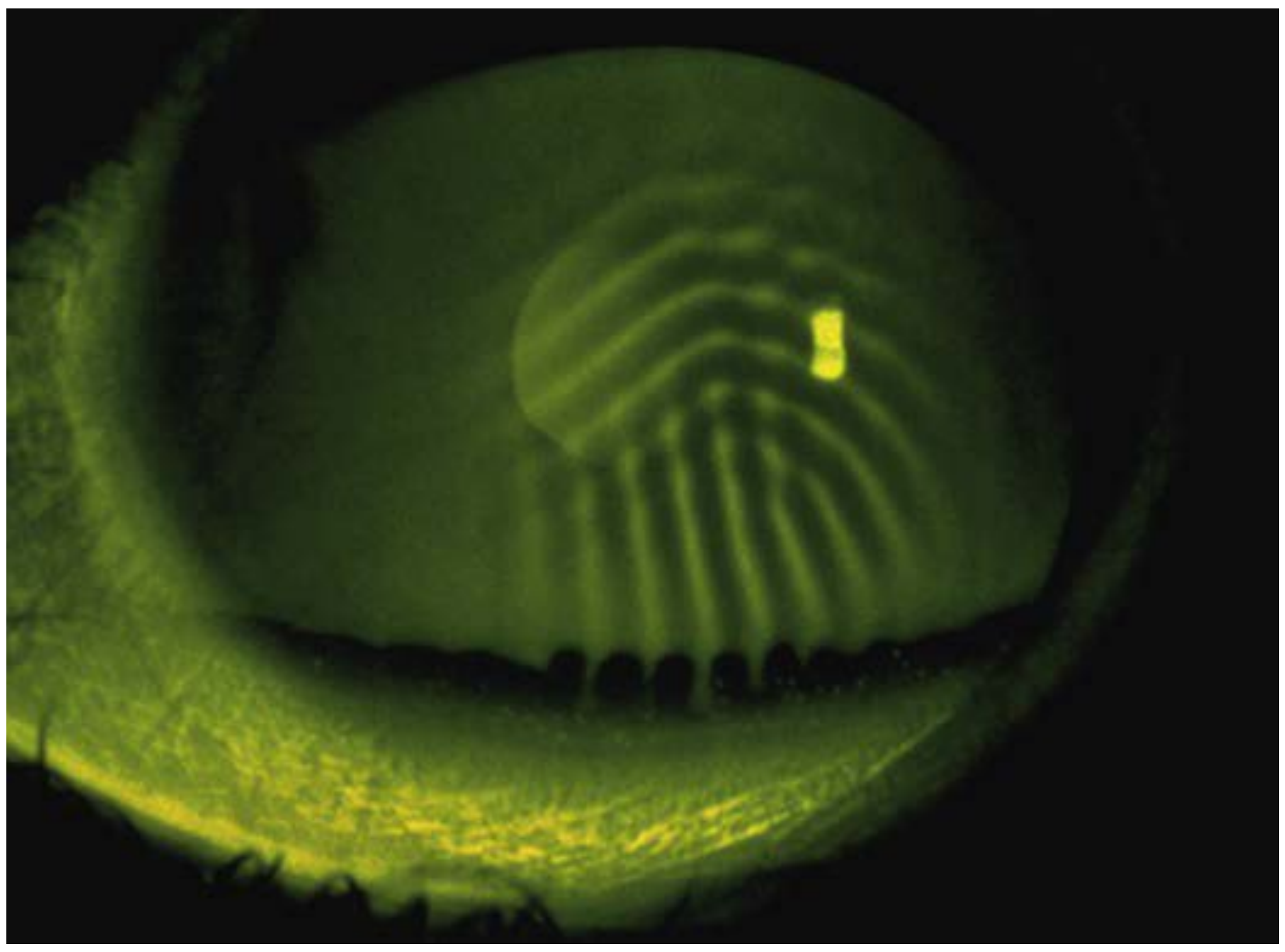

Fig. 40.35 Corneal wrinkling pattern revealed by fluorescein. (Courtesy of Gary Orsborn, Bausch & Lomb Slide Library.)

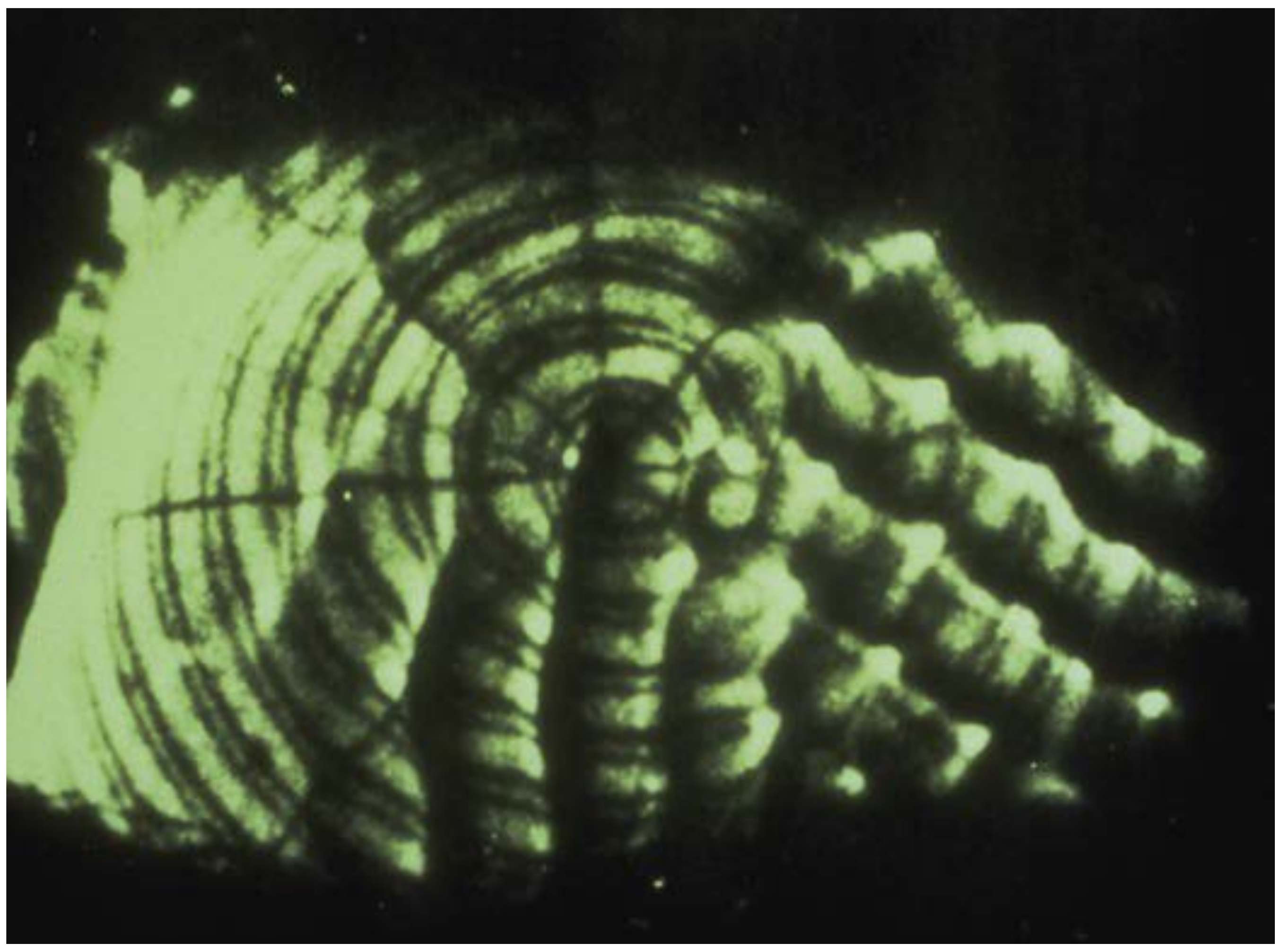

Fig. 40.36 Photokeratogram of cornea showing extreme wrinkling. (Courtesy of Noel Brennan, Bausch & Lomb Slide Library.)

of 70°. Several discrete spots of fluorescence were observed at the points of intersection of the two wave patterns.

This condition is observed in patients wearing steeply fitted, highly elastic, ultrathin, mid-water-content lenses. In the two cases described in the literature (Quinn, 1982; Lowe and Brennan, 1987), the lenses that induced corneal wrinkling were custom made and were not standard commercial products. Excessive elastic forces are thought to draw corneal tissue inwards from the limbus, causing the cornea essentially to 'collapse' in a concertina-like fashion, creating a wrinkled appearance. These forces could be derived from intrinsic elastic energy created when a relatively steep lens is compressed against the eye and then attempts to return to its original shape, and it is noteworthy in this regard that the lens used by Lowe and Brennan (1987) had a fairly steep base curve of 8.20 mm. Corneal wrinkling may also have an osmotic aetiology in view of the observation that complete evaporation of the tear film in normal humans can cause an almost identical corneal wrinkling and vision loss to lens-induced wrinkling.

As one would expect with such a dramatic distortion of the corneal surface, vision loss is substantial. Indeed, vision drops to less than 6/60 within 5 minutes of lens insertion. The condition is also extremely painful. Clinical evaluation of corneal wrinkling is best achieved by slit-lamp examination under white light and with fluorescein under cobalt blue light. Corneal topography can provide useful supplementary information by viewing both the unprocessed image of the reflected mires and the processed, colour-coded surface map.

Lowe and Brennan (1987) argue that corneal wrinkling involves the epithelium and anterior stroma. This view is based upon their observations of the extreme variance in intensity of fluorescence across the ridges of a wrinkled cornea (Fig. 40.35), implying deep furrows, and the extreme distortion of photokeratometric mires (Fig. 40.36). The intensity of the wrinkling pattern increased with time following a blink, indicating fluorescein pooling within deep troughs.

The treatment protocol for a patient experiencing corneal wrinkling is to cease lens wear immediately. Although the appearance of wrinkling will indeed have disappeared within 24 hours, the patient should not wear lenses for 1 week as a precaution so as to allow possible subclinical compromise to resolve. The patient should then be refitted with a soft lens that is devoid of inherently high elastic forces. Alternatively, rigid lenses can be fitted because corneal wrinkling does not occur with such lenses.

The time course of recovery of corneal wrinkling has been demonstrated to be directly related to the period of lens wear that induced the changes. Lowe and Brennan (1987) noted that corneal wrinkling took 3, 90 and 240 minutes to recover following 5, 90 and 300 minutes of lens wear, respectively.

Corneal Stroma

The stroma constitutes 90% of corneal thickness and is a key component of the structural integrity of the globe. As it is normally clear and transparent, the stroma can be directly observed in exquisite detail with the slit-lamp biomicroscope and confocal microscope, providing a privileged insight into adverse tissue reactions (and a decided clinical decision-making advantage) that is not available during the examination of other tissues in the human body.

OEDEMA

Oedema refers to an increase in the fluid content of tissue. Since the cornea is able to swell only in the anterior–posterior direction – as a result of the collagen fibre network in the stroma – the physical dimensions of the cornea can increase only in that dimension – that is, in thickness. The human cornea experiences about 3.5% oedema during sleep. With hydrogel lenses, daytime corneal oedema typically varies between 1 and 6%, and the level of overnight oedema measured upon awakening generally falls in the range 5–13% (Holden et al., 1983). Silicone hydrogel lenses induce less than 4% overnight oedema, which is only a slightly higher rate than occurs when sleeping without lenses (Sweeney et al., 2004; Martin et al., 2008).

Clinicians can estimate the magnitude of corneal oedema by careful observation with the slit-lamp biomicroscope, as a number of structural changes can be identified that correlate with various levels of oedema. Using direct focal illumination, striae appear as fine, wispy, white, vertically oriented lines in the posterior stroma when the level of oedema reaches about

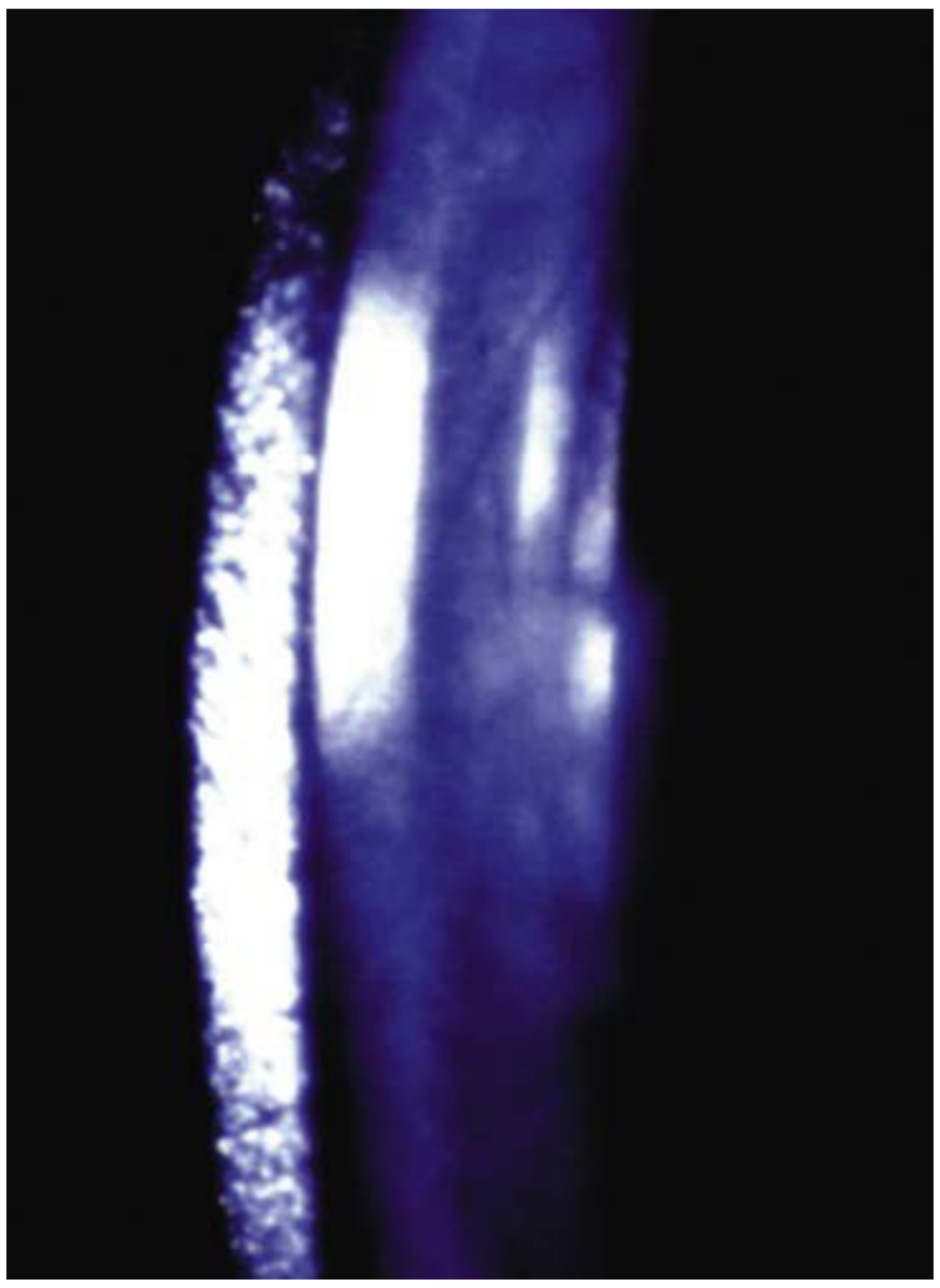

Fig. 40.37 Stromal folds observed using a slit-lamp biomicroscope (×30). (Courtesy of Michael Hare.)

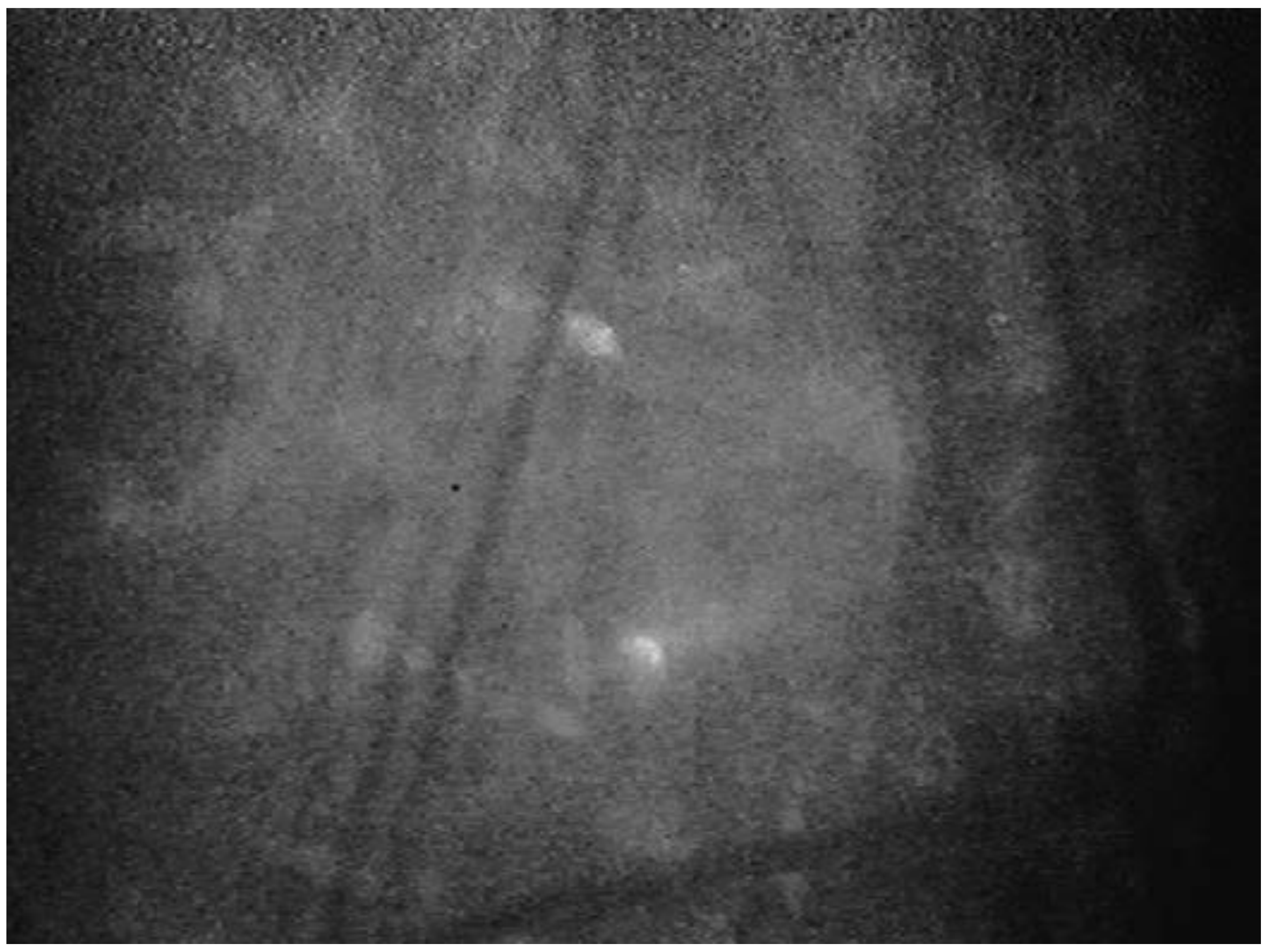

Fig. 40.38 Stromal folds observed using a confocal microscope (×680).

5% (grade 2). Striae are thought to represent fluid separation of the predominantly vertically arranged collagen fibrils in the posterior stroma. Folds can be observed – using specular reflection technique – in the endothelial mosaic as a combination of depressed grooves or raised ridges, or as a general area of apparent buckling, when the level of oedema reaches about 8% (grade 3) (Fig. 40.37). It is thought that folds indicate a physical buckling of the posterior stromal layers in response to high levels of oedema. Folds can also be observed with the confocal microscope as a series of parallel lines crossing the stroma orthogonally (Fig. 40.38). The stroma takes on a hazy, milky or granular appearance when the level of oedema reaches about 15% (grade 4); such high levels of oedema are often associated with other signs and symptoms of ocular distress.

Contact lenses potentially restrict corneal oxygen availability, creating a hypoxic environment at the anterior corneal surface. To conserve energy, the corneal epithelium begins to respire anaerobically. Lactate, a byproduct of anaerobic metabolism, increases in concentration and moves posteriorly into the corneal stroma. This creates an osmotic load that is balanced by an increased movement of water into the stroma. The sudden influx of water cannot be matched by the removal of water from the stroma by the endothelial pump, resulting in corneal oedema (Klyce, 1981).

The key strategy for reducing the oedema response is to increase corneal oxygen availability during lens wear (Morgan et al., 2010). Rigid lens oedema can be alleviated by increasing lens oxygen transmissibility; or fitting a lens of flatter base curve, greater edge lift or smaller diameter so as to increase lens-mediated tear exchange. Hydrogel soft lens oedema can be alleviated by hydrogel lenses of higher oxygen transmissibility, flattening the base curve or reducing lens diameter. General strategies for reducing oedema include changing from extended to daily wear, changing from soft to rigid lenses, fitting silicone hydrogel lenses, and reducing wearing time.

In general, the prognosis for recovery of the cornea from lens-induced oedema is excellent. The oedema induced when a patient wears a contact lens for the first time will resolve within 4 hours of the lens being removed. Chronic lens-induced oedema can take up to 7 days to resolve (Holden et al., 1985a).

THINNING

Although low levels of oedema during the day may appear to be harmless, there is a growing body of evidence indicating that chronic oedema may compromise the physiological integrity of the cornea in the long term. It is now clear that long-term wear of conventional hydrogel lenses can induce thinning of the stroma. Whereas the extent of stromal oedema varies with the prevailing level of corneal oxygenation and dissipates upon removal of hypoxic stress, stromal thinning is a chronic and irreversible tissue change observed in patients who have worn lenses for many years.

Stromal thinning was formally defined for the first time by Holden et al. (1985a), although it had been reported anecdotally by earlier workers. Holden et al. (1985a) detected stromal thinning by measuring the presenting corneal thickness of patients who had been wearing a lens in one eye only on an extended-wear basis for an average of 5 years, because of unilateral myopia or amblyopia. Upon ceasing lens wear, it was noted that corneal thickness in the lens-wearing eye decreased to a steady-state level that was thinner than the fellow non-wearing eye. Assuming that the corneas of both eyes were the same prior to lens wear (this was validated in a non-lens-wearing control group of unilateral myopes and amblyopes), the only assumption that can be drawn is that contact lenses induce stromal thinning.

The revelation of stromal thinning has facilitated interpretation of data from earlier longitudinal lens-wearing studies that incorrectly ascribed a progressive decrease in corneal thickness over time as representing some form of adaptation. Iskeleli et al. (2006) found that central corneal thickness was significantly thinner in patients wearing long-term low-oxygen-transmissibility rigid lenses compared with no contact lens wear and soft contact lenses with a water content of 55%. Central corneal thickness was also decreased significantly in long-term soft contact lens wear, with a water content of 38% compared with 55% in non-wearers.

Contact-lens-induced stromal thinning can be of clinical significance. For example, patients who have worn contact lenses

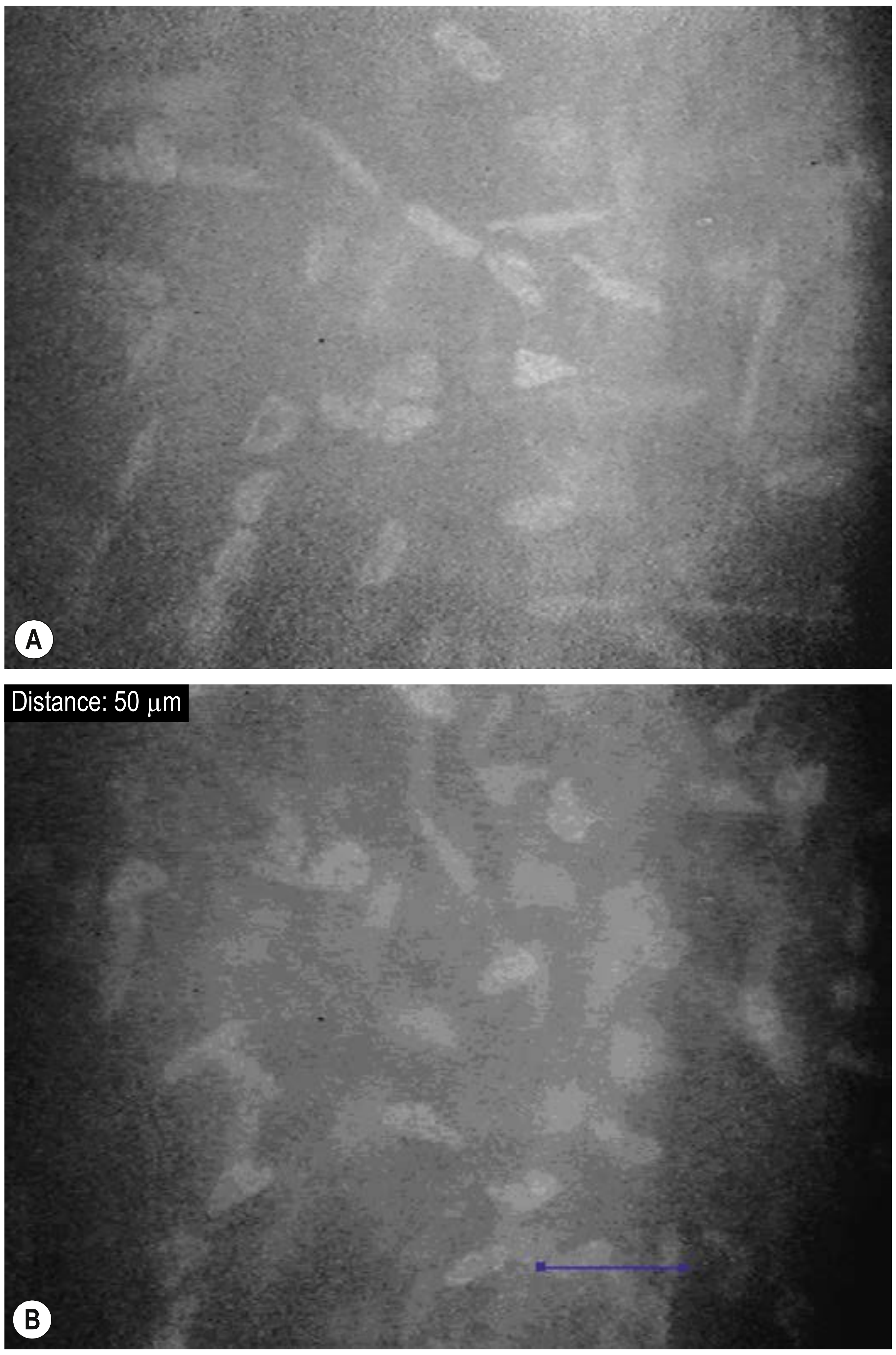

Fig. 40.39 (A) Confocal microscopic images of the posterior stroma in a contact lens wearer. (B) An age- and sex-matched non-lens-wearing control individual. (×300.) (Courtesy of Haliza Mutalib, Bausch & Lomb Slide Library.)

for many years may be precluded from undergoing laser ablative refractive surgery if too much thinning has occurred.

The phenomenon of contact-lens-induced stromal thinning does not confound or invalidate interpretation of the clinical signs of oedema discussed above. Striae, folds and haze represent a given level of oedema irrespective of whether or not the stroma has thinned.

It is presumed that stromal thinning is due to the effects of chronic oedema, and two mechanisms may be postulated to explain how this might occur. First, stromal keratocytes may lose their ability to synthesize new stromal tissue owing to the direct effects of tissue hypoxia, and/or the indirect effects of chronic lens-induced tissue acidosis due to an accumulation of lactic acid and carbonic acid. Second, constantly elevated levels of lactic acid associated with chronic oedema may lead to some dissolution of the mucopolysaccharide ground substance of the stroma. Recent evidence obtained using confocal microscopy, demonstrating loss of stromal keratocytes following hydrogel lens wear (Jalbert and Stapleton, 1999; Efron et al., 2001; Kallinikos and Efron, 2004; Kallinikos et al., 2006), lends support to the former theory (Fig. 40.39).

DEEP STROMAL OPACITIES

A number of authors have noted apparently benign, deep stromal opacities (DSOs) in the corneas of contact lens wearers (Brooks et al., 1986; Gobbels et al., 1989; Remeijer et al., 1990; Loveridge and Larke, 1992; Holland et al., 1995; Pimenides et al., 1996). The opacities have been variously described as being white, grey, brown, blue and cyan in colour, and cloudy, scar-like, lattice-like and stellate-like in form. They are sometimes associated with folds and striae in Descemet's layer, and with deep stromal vascularization (Loveridge and Larke, 1992). It is possible to distinguish DSOs from infiltrates (which typically reside in the anterior half of the stroma) because DSOs are invariably located deep in the stroma (Fig. 40.40). However, DSOs can take on a similar appearance to certain forms of posterior stromal dystrophy, and some of the reported cases of DSO may have been confused with dystrophies. The aetiology of this condition is unknown but probably varied (Loveridge and Larke, 1992).

Examination of the living human cornea at very high magnification (680×) using a confocal microscope has revealed the presence of highly reflective 'microdot deposits' throughout the corneal stroma (Böhnke and Masters, 1997; Trittibach et al., 2005) (Fig. 40.41); these microdots may be a subclinical correlate of DSOs. According to Böhnke and Masters (1997), microdots are small, discrete, brightly reflective spots or dots scattered throughout the stroma; they are generally round or oval in shape, and vary in diameter from about 1 μm to 4 μm. In patients who had worn soft contact lenses for an average of 26 years, panstromal microdot deposits were observed with a mean grade of 3.1 (range 1–4). In the control group, none of 29 patients had stromal microdot deposits. The authors concluded that stromal microdot degeneration may be the early stage of a significant corneal disease, which eventually may affect large numbers of patients after decades of contact lens wear.

Mutalib (2000) conducted an experiment in an attempt to replicate the findings of Böhnke and Masters (1997). The corneas of one eye of 13 patients (age 32 ± 7 years) who had worn contact lenses for an average of 8.2 years were imaged using the confocal microscope, as were the corneas of one eye of 13 age- and sex-matched control individuals who had never worn contact lenses. Microdot deposits were observed in the stroma of all 13 lens wearers, with a mean severity of grade 2.0 ± 1.1. In the control group, microdots were observed in 10 of the 13 subjects, with a mean severity in the 10 eyes displaying microdots of 1.5 ± 0.7. The difference in the severity of microdots was statistically significant. The microdots had an identical appearance in lens-wearing and control individuals, apart from the difference in grading. They were all fairly similar in size (1–2 μm diameter).

The fact that microdot deposits are observed in all individuals, whether contact lenses have been worn or not, suggests that this phenomenon cannot be properly characterized as a disease (Efron, 2005). However, the higher grading assigned to microdots in lens wearers indicates that contact lens wear is exacerbating otherwise-normal corneal morphological features. Deep corneal opacities seen with the slit-lamp biomicroscope may be a gross manifestation of microdot formation – for example, by way of a massive aggregation of microdots in the deep stroma.

It should also be recognized that it is not possible at present to determine whether the appearance of DSOs and of microdots

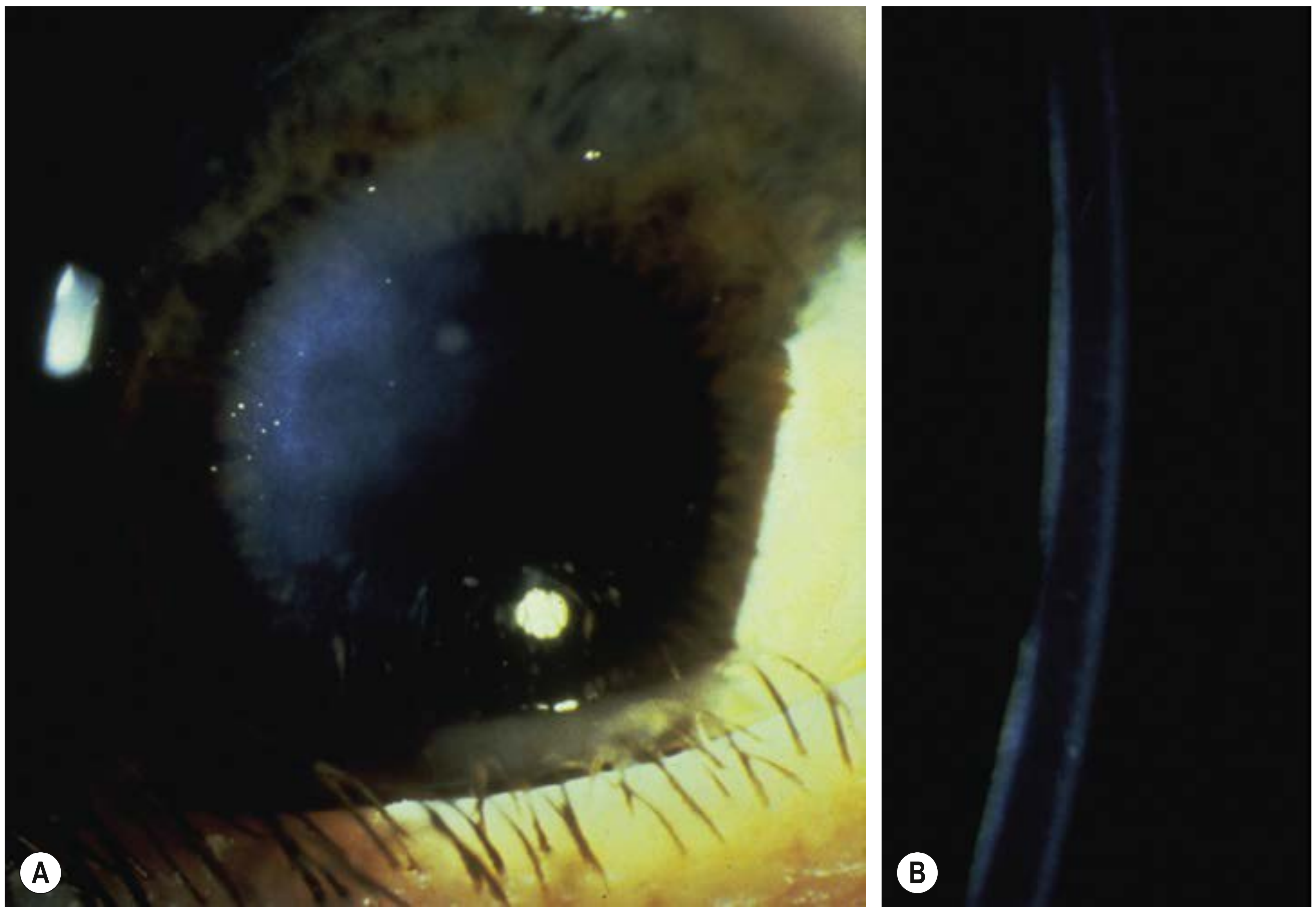

Fig. 40.40 Deep stromal opacities in a 24-year-old woman who had worn 38%-water-content hydroxyethyl methacrylate (HEMA) lenses for 4 years. (A) Seen as a grey haze with a broad slit-lamp beam. (B) A slit-lamp view confirms that the opacities are deep in the stroma. The condition resolved 2 months after ceasing lens wear. (Courtesy of F. E. Ros, Bausch & Lomb Slide Library.)

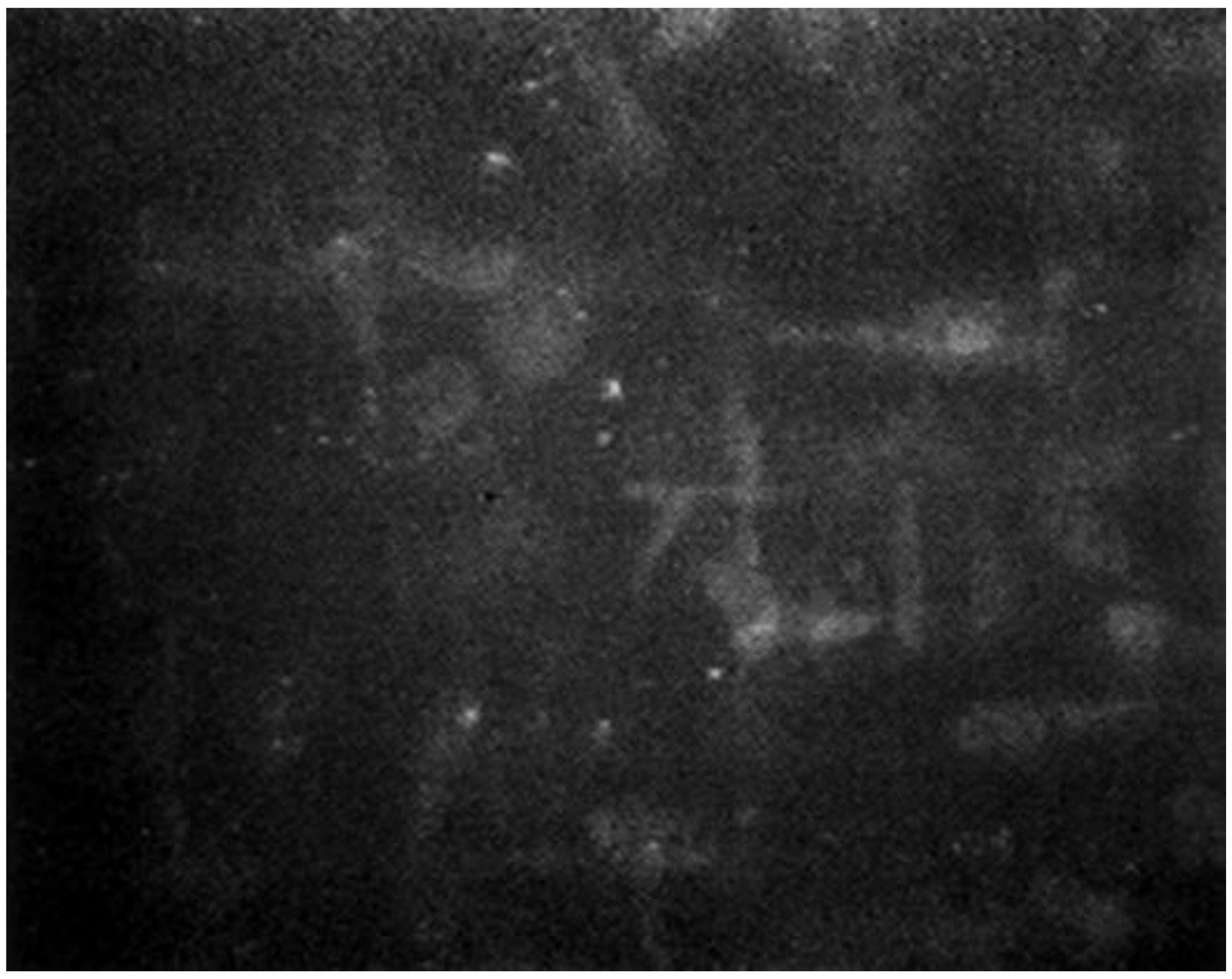

Fig. 40.41 Microdot deposits (bright white spots) observed in the posterior stroma of a contact lens wearer. (Courtesy of Haliza Mutalib, Bausch & Lomb Slide Library.)

is related to the contact lenses or to solutions used in conjunction with lens wear.

NEOVASCULARIZATION

Corneal neovascularization can be defined as the formation and extension of vascular capillaries within and into previously avascular regions of the cornea. Superficial neovascularization is the most common of the various forms of contact-lens-induced vascular response (Fig. 40.42). Vision loss is rare and will only occur if vessels encroach the pupillary axis or if there has been an extensive leakage of lipid into the stroma (grade 4). Deep stromal neovascularization develops insidiously, usually in an already-compromised cornea (e.g. keratoconus), and may also progress in the absence of acute symptoms (Shah et al., 1998) (Fig. 40.43).

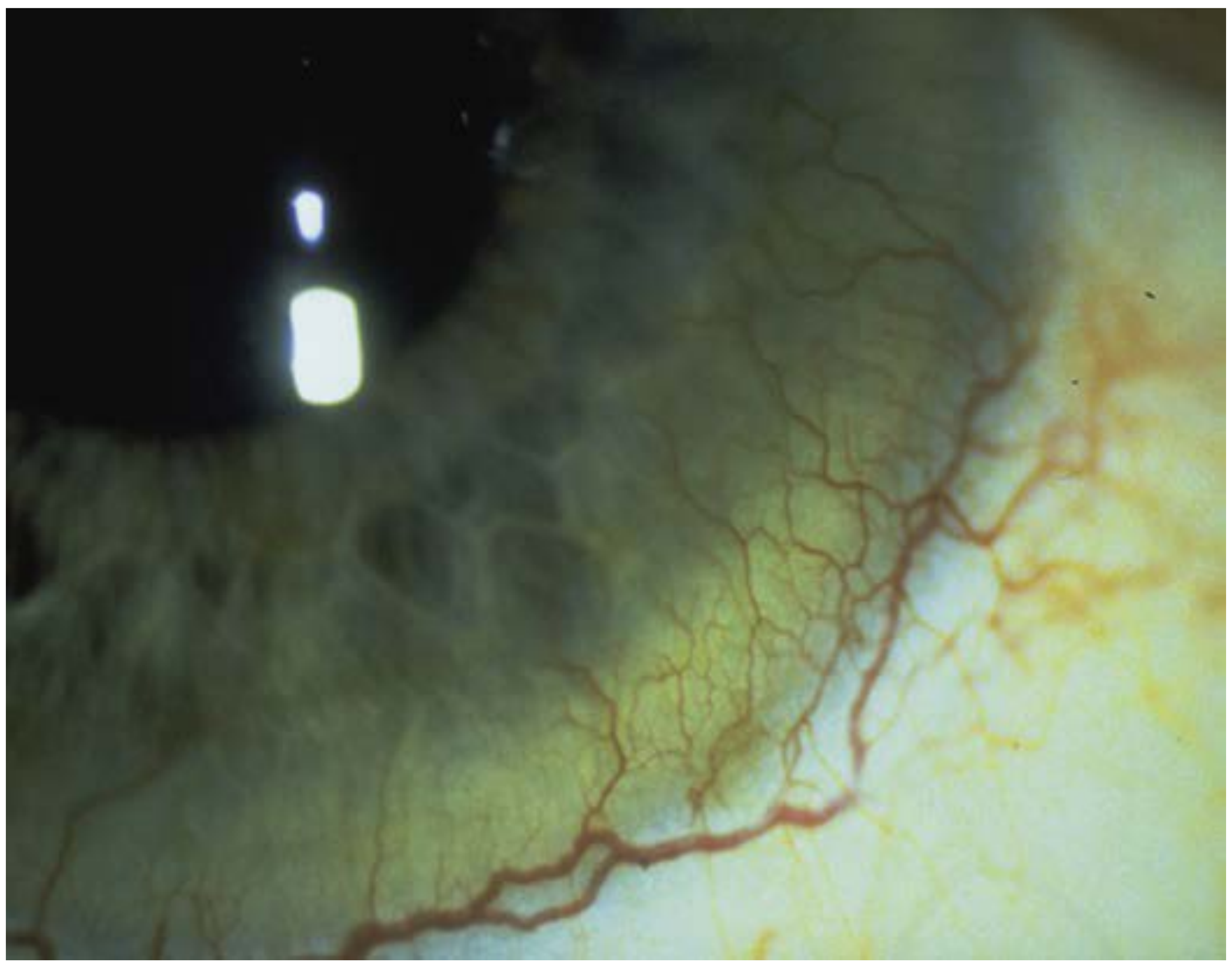

Fig. 40.42 Superficial stromal neovascularization.

A pannus is a thick plexus of vessels typically observed at the superior limbus. Two forms of pannus may be observed in contact lens wearers: active (inflammatory) and fibrovascular (degenerative). An active pannus is avascular and is composed of subepithelial inflammatory cells. In the later stages it may be associated with secondary scarring of the stroma.

In contact-lens-induced corneal neovascularization, vessel lumina are approximately 15–80 μm in diameter and contain erythrocytes and sometimes leukocytes. Numerous extravascular leukocytes are observed around blood vessels, and the

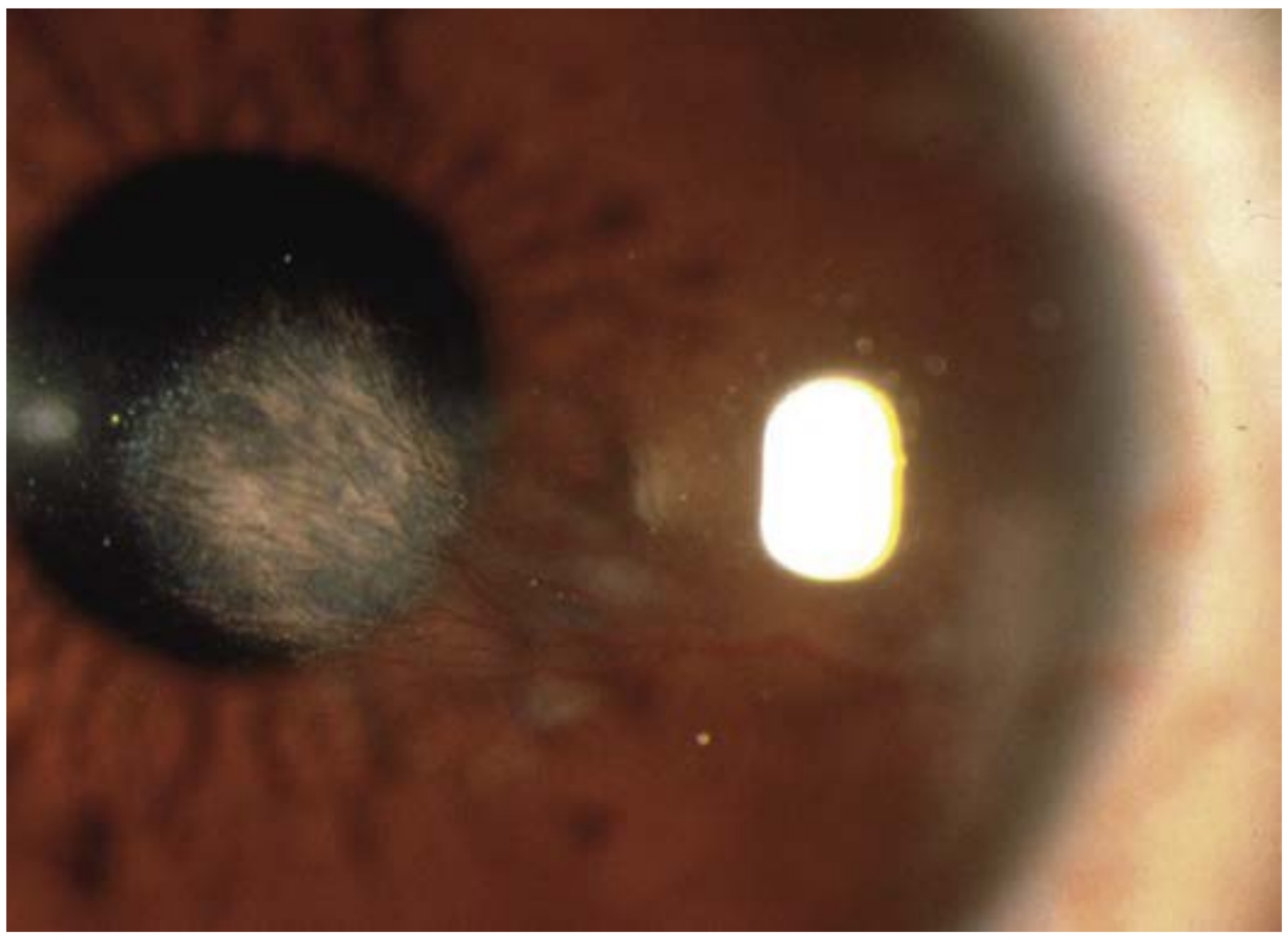

Fig. 40.43 Deep stromal neovascularization, progressing to the site of a corneal ulcer. (Courtesy of Barry Weissman.)

surrounding stromal lamellae are disorganized and separated with lines of keratocytes lying between them. The overlying corneal epithelium is often affected, with general oedema, cell loss and the presence of large fluid-filled vesicles. The underlying Descemet's layer and endothelium are apparently unaffected (Madigan et al., 1990).

Contact-lens-induced corneal neovascularization can be explained in terms of a dual aetiology model. Chronic hypoxia induces stromal oedema, which 'softens' the stroma and renders this tissue more susceptible to vascular penetration. Some secondary factor must act to stimulate vessel growth – for example, this could be mechanical injury to the epithelium, resulting in a release of enzymes. Inflammatory cells migrate to this site and release vasostimulating agents that cause vessels to grow in that direction.

Efron (1987) reviewed the early literature and calculated that the limits of 'normal' or 'expected' vascular ingrowth (i.e. less than grade 1), measured from the limit of visible iris, were 0.2, 0.4, 0.6 and 1.4 mm for no wear, daily-wear rigid, daily-wear hydrogel and extended-wear hydrogel regimens, respectively. There have been no reports of neovascularization being induced by silicone hydrogel lenses since their introduction to the market at the turn of the century (Sweeney, 2013).

If corneal neovascularization is a primary concern, the prescription of lenses with design features known to provide minimal interference with corneal physiology is indicated, namely: high oxygen transmissibility (such as silicone hydrogel lenses or high-oxygen-transmissibility rigid lenses, to minimize oedema and metabolic acidosis), minimal mechanical effect (as judged by patient comfort) and good movement (to avoid venous stasis resulting from limbal compression in soft lenses). Care systems likely to induce toxic or allergic responses should be avoided, and regular aftercare visits are essential. Other options to be considered include changing from extended wear to daily wear, replacing lenses more frequently, reducing wearing time or even ceasing lens wear.

Cessation of lens wear will halt the progression of vessel infiltration into the cornea, but empty 'ghost' vessels may remain in place for months or years. Resumption of lens wear in a previously vascularized cornea will result in immediate refilling of the vessels. Thus, in advanced cases of neovascularization, long-term cessation of lens wear is indicated until ghost vessels can no longer be detected.

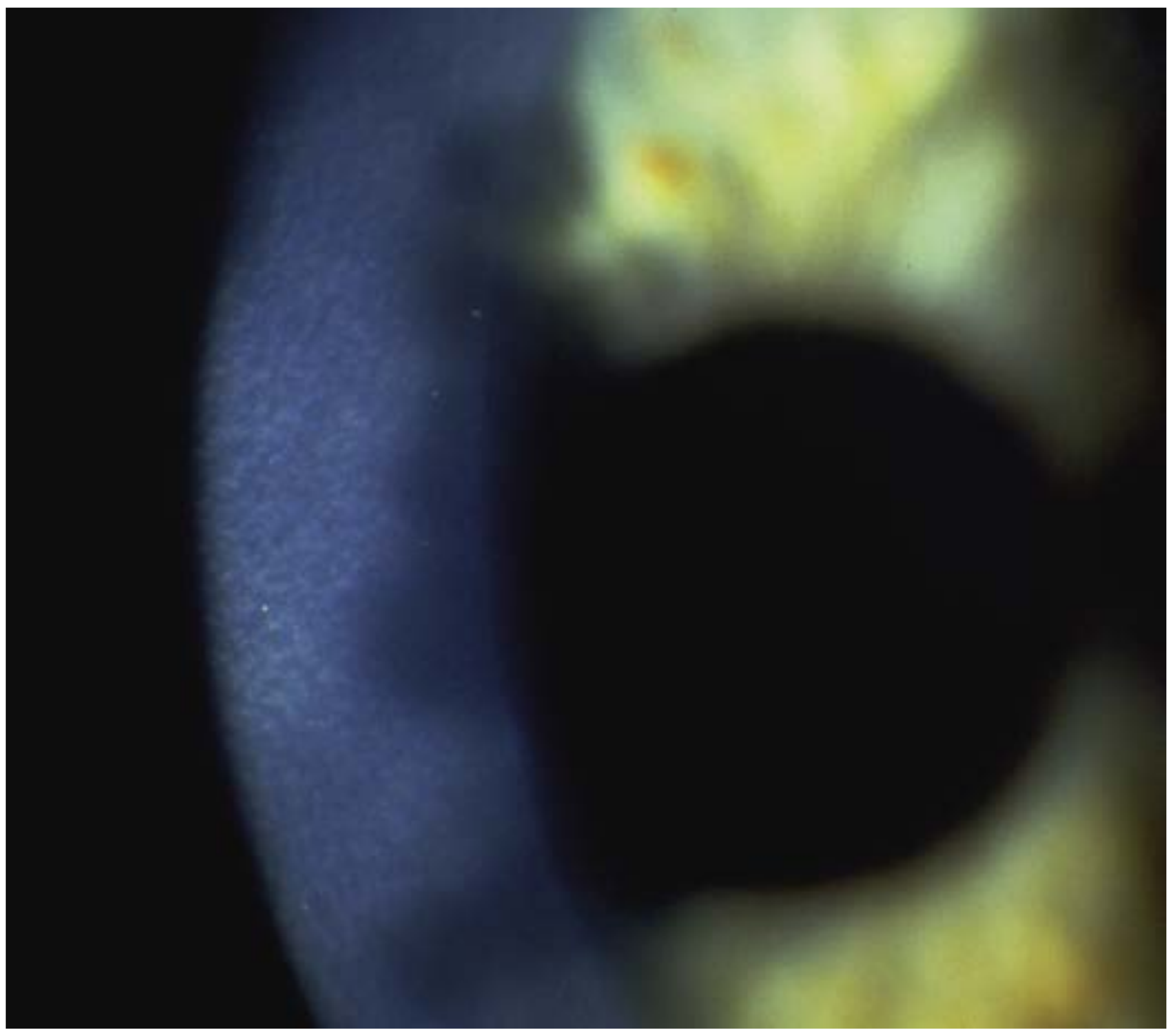

Fig. 40.44 Broad band of sterile infiltrative keratitis in a soft lens wearer attributed to hypoxia. (Courtesy of Luigina Sorbara, Bausch & Lomb Slide Library.)

KERATITIS

Keratitis refers to inflammation of the cornea. From the perspective of the aetiology and pathology of contact-lens-associated keratitis, it is possible to characterize a condition as being either sterile (non-infectious) or microbial (infectious). However, the difficulty with this approach is that, from a clinical perspective, it is virtually impossible to distinguish between the two in the early stages of the disease. To complicate matters further, it has been suggested that sterile keratitis can be classified into four subgroups: the so-called contact lens peripheral ulcer, contact lens-associated red eye, infiltrative keratitis and asymptomatic infiltrative keratitis (Sweeney et al., 2003). Subsequent research has shown, however, that these entities cannot be readily differentiated (Efron and Morgan, 2006a). This approach has now been largely abandoned in favour of considering all corneal infiltrative events – from the mildest symptomatic infiltrate to severe microbial keratitis – as a potential disease continuum, and to treat less-severe events with caution, as possible precursors to microbial keratitis (Efron and Morgan, 2006b).

From an aetiological perspective, contact lens-associated sterile keratitis can result from a variety of mechanisms, such as solution toxicity, bacterial endotoxicity (as distinct from infectivity), immunological reaction, trauma, hypoxia and metabolic disturbance (Fig. 40.44). Other aetiological factors include breakdown of trapped post-lens tear film debris, lens deposits and poor patient hygiene. The condition may be ulcerative (Fig. 40.45) or non-ulcerative.

Histopathological analysis of human tissue from patients suffering from sterile keratitis reveals focal areas of epithelial loss, attenuated epithelium and stromal infiltration with polymorphonuclear leukocytes; Bowman's layer is unaffected (Holden et al., 1999).

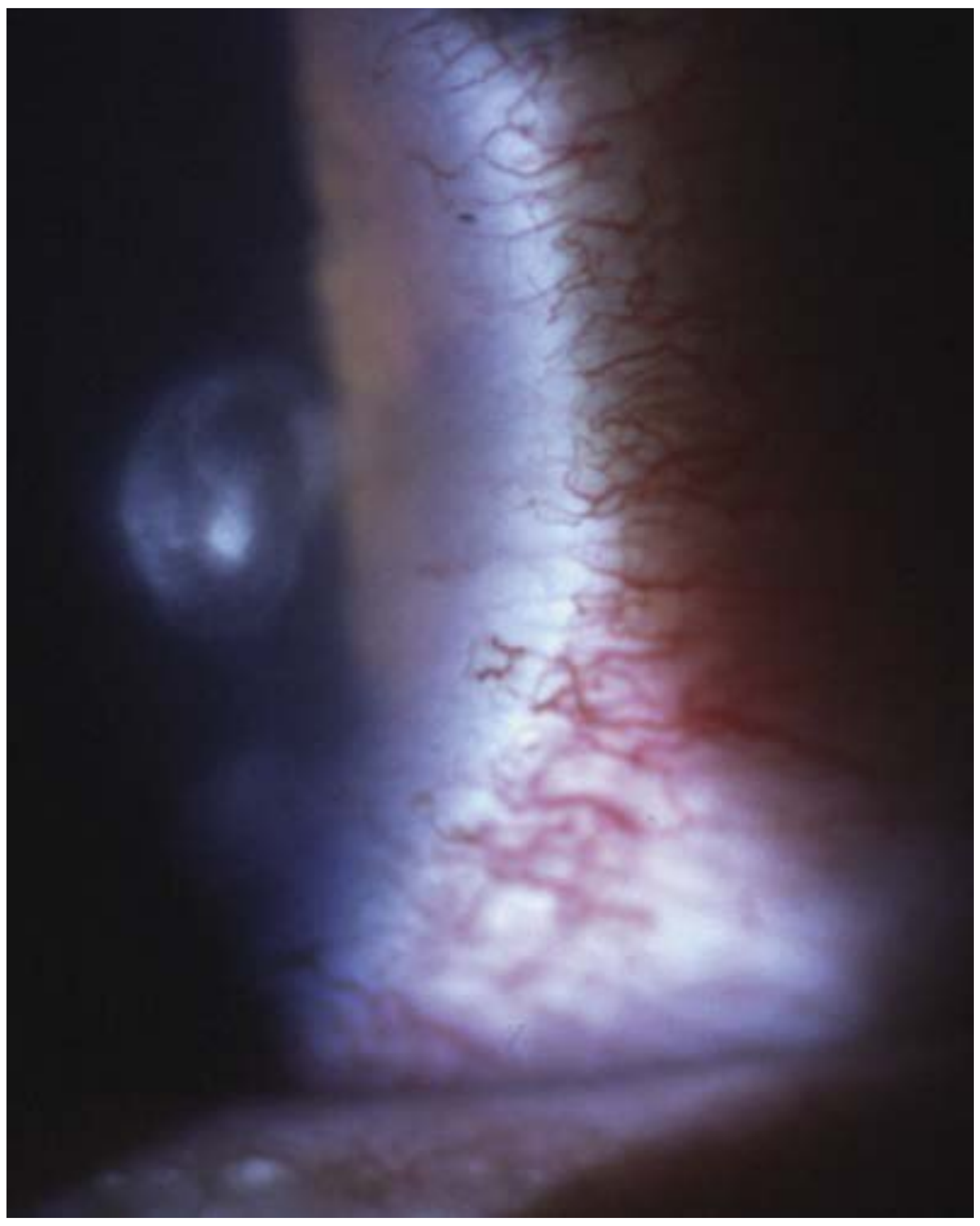

Fig. 40.45 Contact lens-associated sterile ulcerative keratitis. (Courtesy of Michael Hare.)

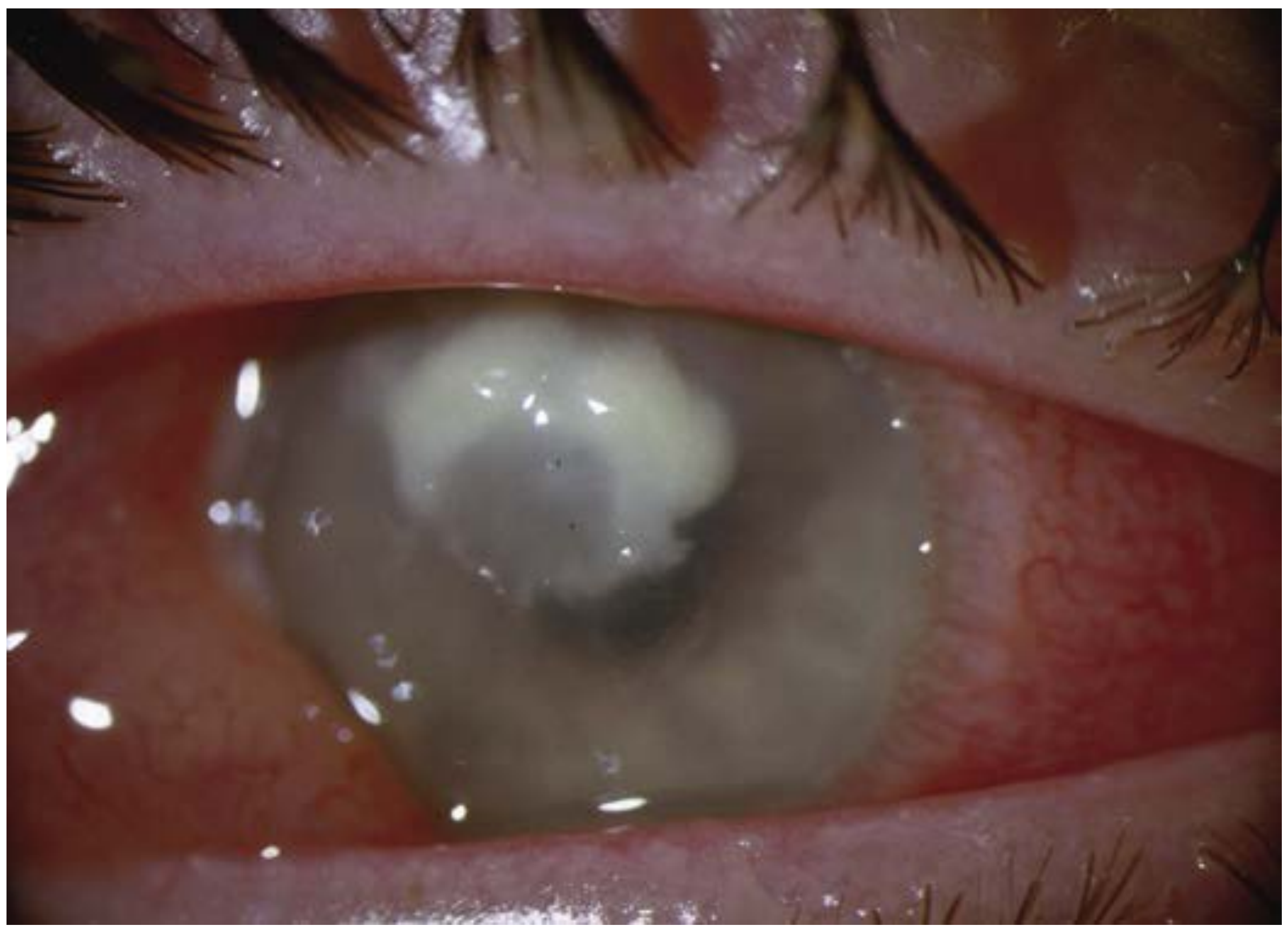

Fig. 40.46 Advanced microbial keratitis in a soft lens wearer. The corneal ulcer displays a 'soupy' appearance typical of Gram-negative bacterial keratitis; the lesion was culture-positive for Pseudomonas aeruginosa. (Courtesy of Barry Weissman.)

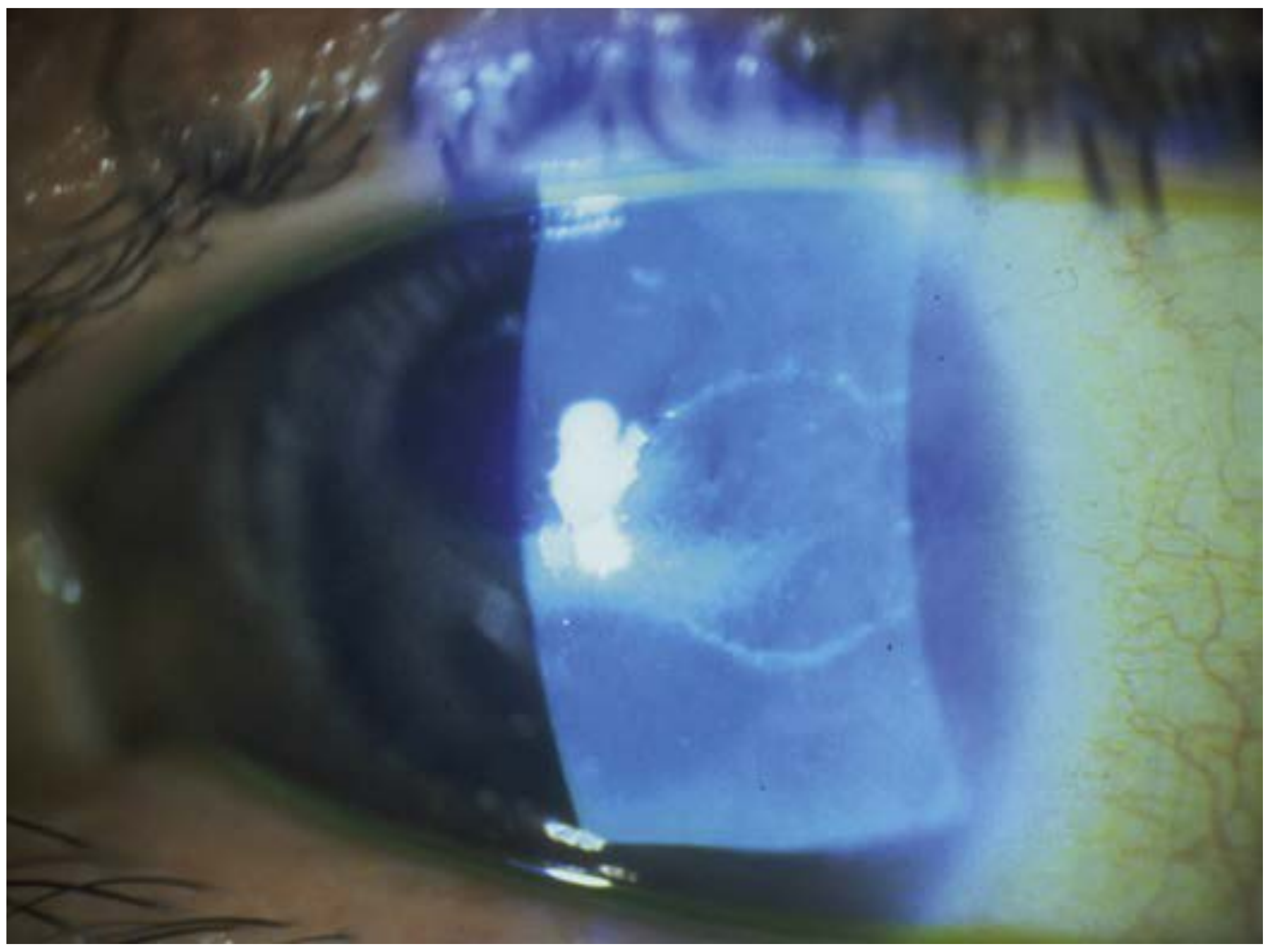

Fig. 40.47 Characteristic pattern of radial keratoneuritis in a soft lens wearer with Acanthamoeba keratitis. (Courtesy Florence Malet, Bausch & Lomb Slide Library.)

Contact-lens-associated microbial (infectious) keratitis can be ulcerative (e.g. Pseudomonas aeruginosa keratitis) or non-ulcerative (e.g. epidemic keratoconjunctivitis); the latter form is not caused by contact lens wear and will not be considered further here. A positive culture result for bacteria, virus, fungus or amoeba will provide strong evidence that the keratitis is infectious (microbial), but a negative culture result simply means that microbial agents could not be detected in the tissue. In the latter case, a keratitis may still be classified clinically as 'infectious' based upon associated signs and symptoms (Aasuri et al., 2003).

An early symptom of keratitis is a foreign-body sensation in the eyes associated with an increasing desire to remove the lenses. Continuing or worsening discomfort following lens removal should lead a clinician to suspect microbial keratitis, with associated symptoms including pain, eye redness, swollen lids, increased lacrimation, photophobia, discharge and loss of vision. Conversely, if the condition is self-limiting and signs and symptoms eventually resolve without any clinical or therapeutic intervention, the condition can retrospectively be deemed to have been a case of sterile keratitis. However, a mild keratitis, in the early stages of development, should never be diagnosed as a sterile keratitis (or one of the so-called subcategories referred to above). Sterile keratitis is a condition that can be diagnosed only retrospectively. So, if a patient presents with ocular discomfort and infiltrates are evident in the cornea, no matter how apparently mild or innocuous, the case should be considered as a potential microbial keratitis and managed accordingly (Efron and Morgan, 2006b).

Bacterial keratitis (e.g. Pseudomonas) can have a rapid and devastating time course. Epithelial and stromal haze, lacrimation and limbal redness adjacent to the lesion will be noticed initially, followed by anterior chamber flare, iritis, hypopyon and a serous or mucopurulent discharge. If not properly treated, the stroma can melt away, leading to corneal perforation in a matter of days (Fig. 40.46). The time course of Acanthamoeba keratitis is not as rapid; typical signs include corneal staining, pseudodendrites, epithelial and anterior stromal infiltrates that may be focal or diffuse and a classic radial keratoneuritis – this being a circular formation of opacification that becomes apparent relatively early in the disease process (Fig. 40.47). A fully developed corneal ulcer may take weeks to form (Moore et al., 1985).

The factors leading to the development of microbial keratitis, and strategies for minimizing the risk of developing this condition, are essentially the same as those discussed above in relation to the aetiology of sterile keratitis, with the obvious additional factor of microbial invasion of corneal tissue. Other risk factors for microbial keratitis include male gender, diabetes, tobacco use and travel to warm climates (Morgan et al., 2005).

A corneal scraping is usually performed to determine whether the condition is infectious and possibly to identify the offending microorganism. Medical therapies may include the use of antibiotics, mydriatics, collagenase inhibitors, non-steroidal anti-inflammatory agents, analgesics, tissue adhesives, debridement, bandage lenses and collagen shields. Steroids may be prescribed with extreme caution in the late healing phase so as to dampen the host response. Surgical interventions include penetrating graft, which may need to be performed in the case of large perforations or non-healing deep central ulceration, or possibly lamellar graft. The prognosis for recovery from microbial keratitis is variable, ranging from a few weeks in the case of Pseudomonas keratitis to many months of regression and recurrence in the case of Acanthamoeba keratitis.

WARPAGE

Corneal topography reveals that all forms of contact lens wear are capable of inducing small changes in corneal shape. These shape changes, which are generally referred to as 'warpage', are primarily mediated by the stroma, which is the main structural entity of the cornea (the epithelium and endothelium offer little mechanical resistance to deforming forces).

The degree of irregularity of corneal surface shape can be expressed by various mathematical indices. For example, the surface asymmetry index (SAI) provides a quantitative measure of the radial symmetry of the four central videokeratoscope mires surrounding the vertex of the cornea. The higher the degree of central corneal symmetry, the lower is the SAI. Ruiz-Montenegro et al. (1993) reported SAI mean values (± standard error of mean) associated with the following forms of lens wear: polymethyl methacrylate (PMMA) 0.86 ± 0.22, daily-wear rigid 0.48 ± 0.09, daily-wear hydrogel 0.48 ± 0.11, extended-wear hydrogel 0.46 ± 0.08, and non-lens-wearing controls 0.35 ± 0.03. The SAI was significantly greater than the control group for all forms of lens wear except daily-wear hydrogel.

The surface regularity index (SRI) is a measure of central and paracentral corneal irregularity derived from the summation of fluctuations in corneal power that occur along semi-meridians of the 10 central photokeratoscope mires. The more regular the anterior surface of the central cornea, the lower is the SRI. The SRI is highly correlated with best spectacle-corrected visual acuity. Ruiz-Montenegro et al. (1993) reported SRI mean values (± standard error of mean) associated with the following forms of lens wear: PMMA 1.17 ± 0.34, daily-wear rigid 0.93 ± 0.18, daily-wear hydrogel 0.52 ± 0.08, extended-wear hydrogel 0.51 ± 0.06, and non-lens-wearing controls 0.41 ± 0.04. The SRI was significantly greater than the control group for PMMA and daily rigid lens wear, but not for daily or extended hydrogel lens wear.

All known forms of contact-lens-induced warpage can be explained in terms of three underlying pathological mechanisms that primarily act on the stroma. These mechanisms are: (1) physical pressure on the cornea exerted either by the lens and/or by the eyelids, (2) contact-lens-induced stromal oedema, and (3) mucus binding beneath rigid lenses. The relative contributions of these factors will govern the type and extent of topographical alteration (Carney, 1975).

Rigid lenses can induce clinically significant warpage, which may be especially evident in patients with higher prescriptions requiring thicker lenses or unusual lens designs (Fig. 40.48). Such lenses will impart greater physical and hypoxic stress on the cornea compared with thinner lenses made of the same material. Altering the parameters of a rigid lens can reduce the physical impact of the lens on the cornea and thus minimize corneal shape changes. Of course, in any case of rigid-lens-induced warpage, refitting into soft lenses will usually provide a cure because soft lenses are known to have little or no effect on corneal topography.

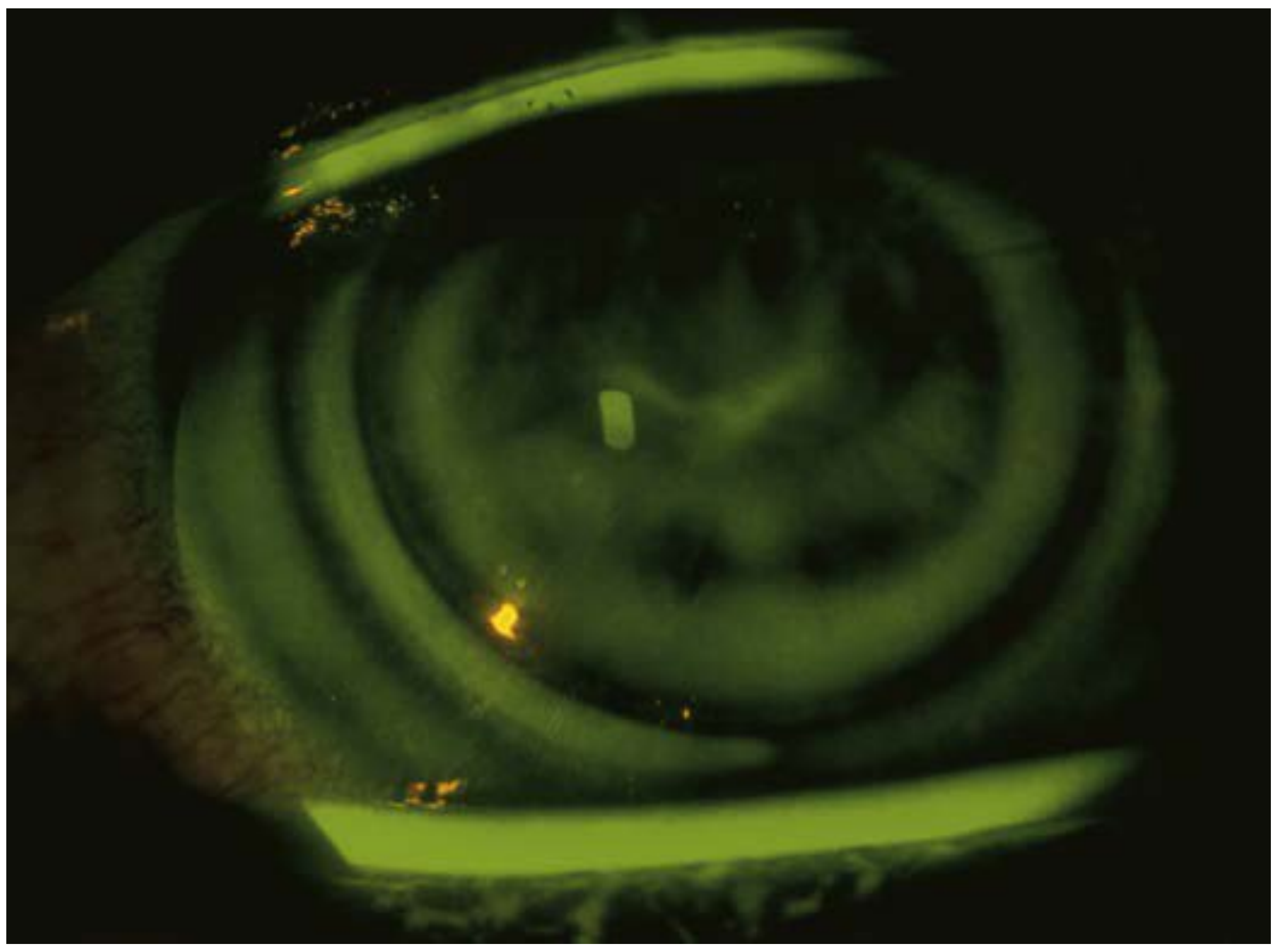

Fig. 40.48 Fluorescein pattern showing severe corneal warpage in the form of several concentric bands of deep corneal indentation. This deformation was evident immediately after removal of an immobile hybrid lens (rigid centre and hydrophilic surround annulus). The patient was keratoconic and required a prescription of −34.00 D. The lens caused extreme pain. (Courtesy of Russell Lowe.)

The prognosis for recovery of normal corneal topography is highly variable and dependent upon the cause, magnitude and duration of the lens-induced deformation. The time course of recovery from physical forces on the cornea is difficult to predict. Recovery from chronic lens-induced oedema is known to occur within 7 days of cessation of lens wear; thus, recovery from oedema-mediated warpage would be expected to follow a similar time course. Hashemi et al. (2008) suggest that a 2-week contact lens-free period is adequate for the cornea to stabilize; however, they suggest that it is difficult to predict the minimum time needed for each individual patient.

Corneal Endothelium

As the tissue layer responsible for corneal hydration control, the endothelium must be kept healthy so as to avoid chronic oedema-related problems and the added risk of compromise during ocular surgery. It is only in the past 30 years that it has been recognized that the endothelium can be affected by contact lens wear.

BEDEWING

Contact-lens-associated endothelial bedewing (CLEB) is characterized by the appearance of small particles in or on the endothelium in the region of the inferior central cornea, immediately below the lower pupil margin (Fig. 40.49). The area of bedewing can vary in shape. For example, CLEB may appear as an oval cluster of particles or a less discrete dispersed formation. The condition is usually bilateral. The cells invariably display reversed illumination (see discussion on microcysts, above, for an explanation of this phenomenon), suggesting that bedewing represents inflammatory cells rather than intracellular endothelial oedema (which would display unreversed illumination).

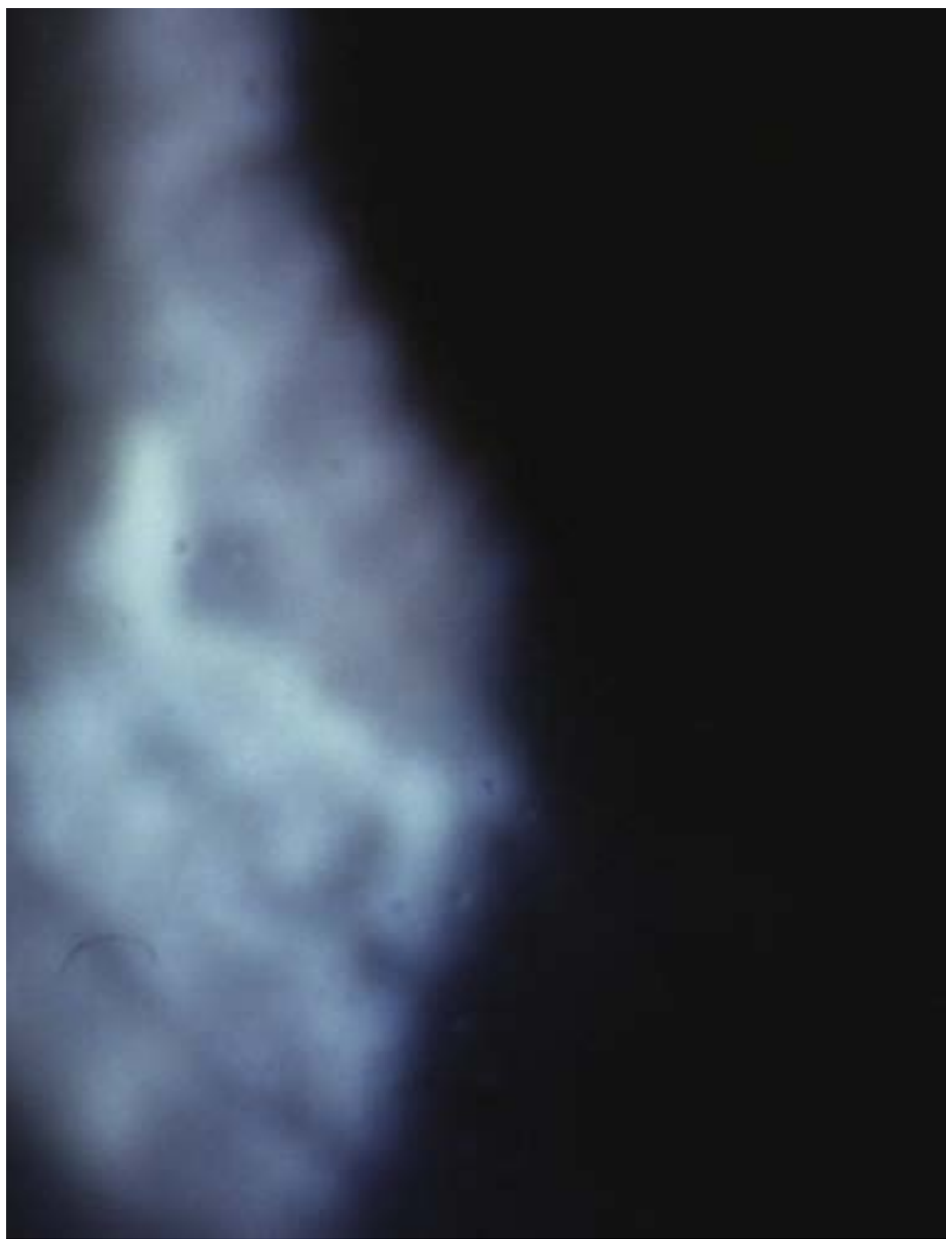

Fig. 40.49 Endothelial bedewing. (Courtesy of Michael Hare.)

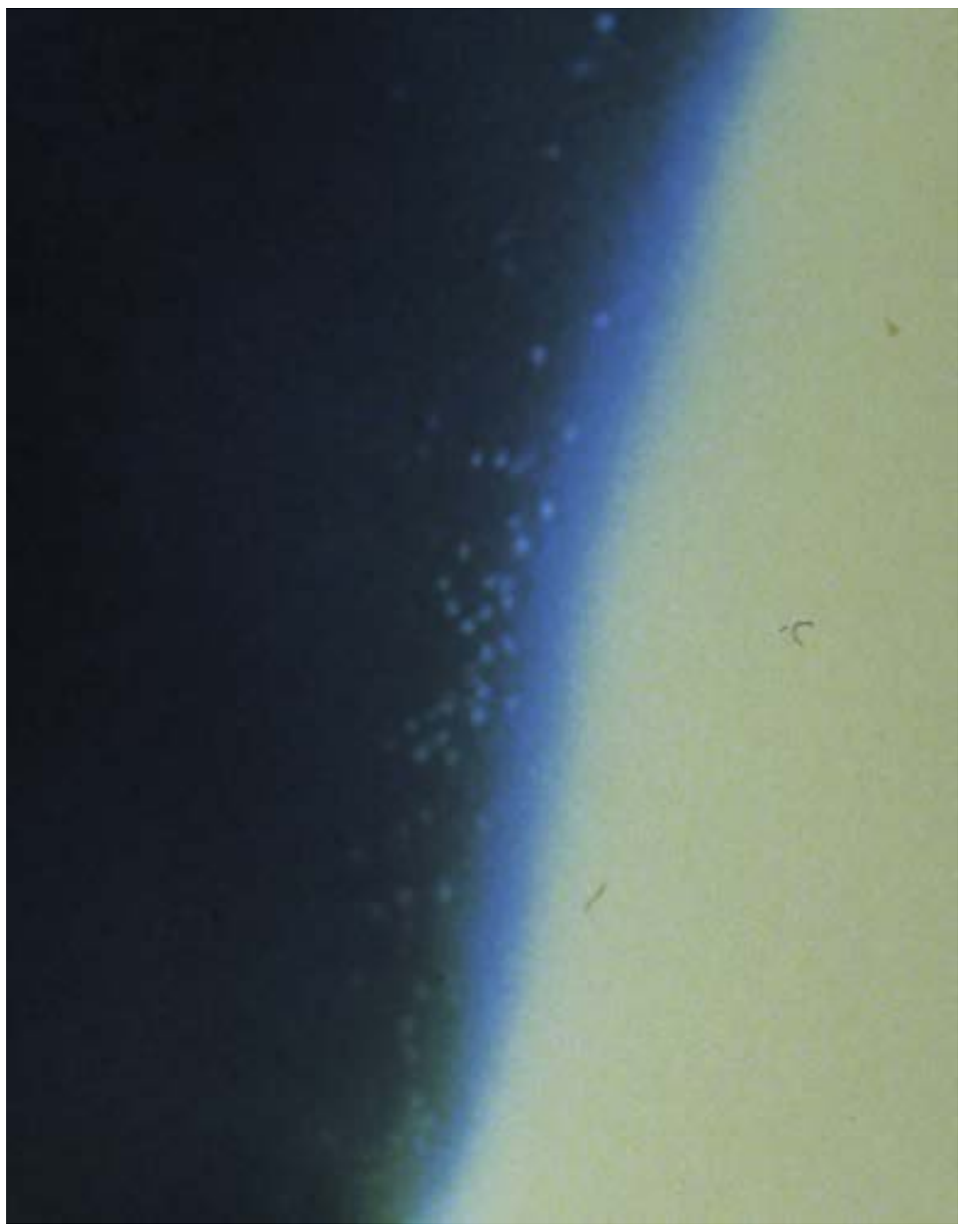

Fig. 40.50 Endothelial bedewing observed at high magnification (×40). (Courtesy of Charles McMonnies.)

When viewed in direct illumination, CLEB can appear as fine white precipitates or as an orange/brown dusting of cells. The colour of the particles can give a clue to the length of time they have been present; newly deposited cells are often whitish in colour (Fig. 40.50), but these become pigmented over time. The cells can become engulfed within the endothelium over time (Bergmanson and Weissman, 1992).

The following signs may coexist with CLEB: conjunctival injection, epithelial erosion, epithelial oedema and reduced corneal transparency. The main associated feature of endothelial bedewing is either total or partial intolerance to lens wear. Some patients may present after having recently abandoned lens wear. Patients may also complain of 'fogging' of vision or stinging.

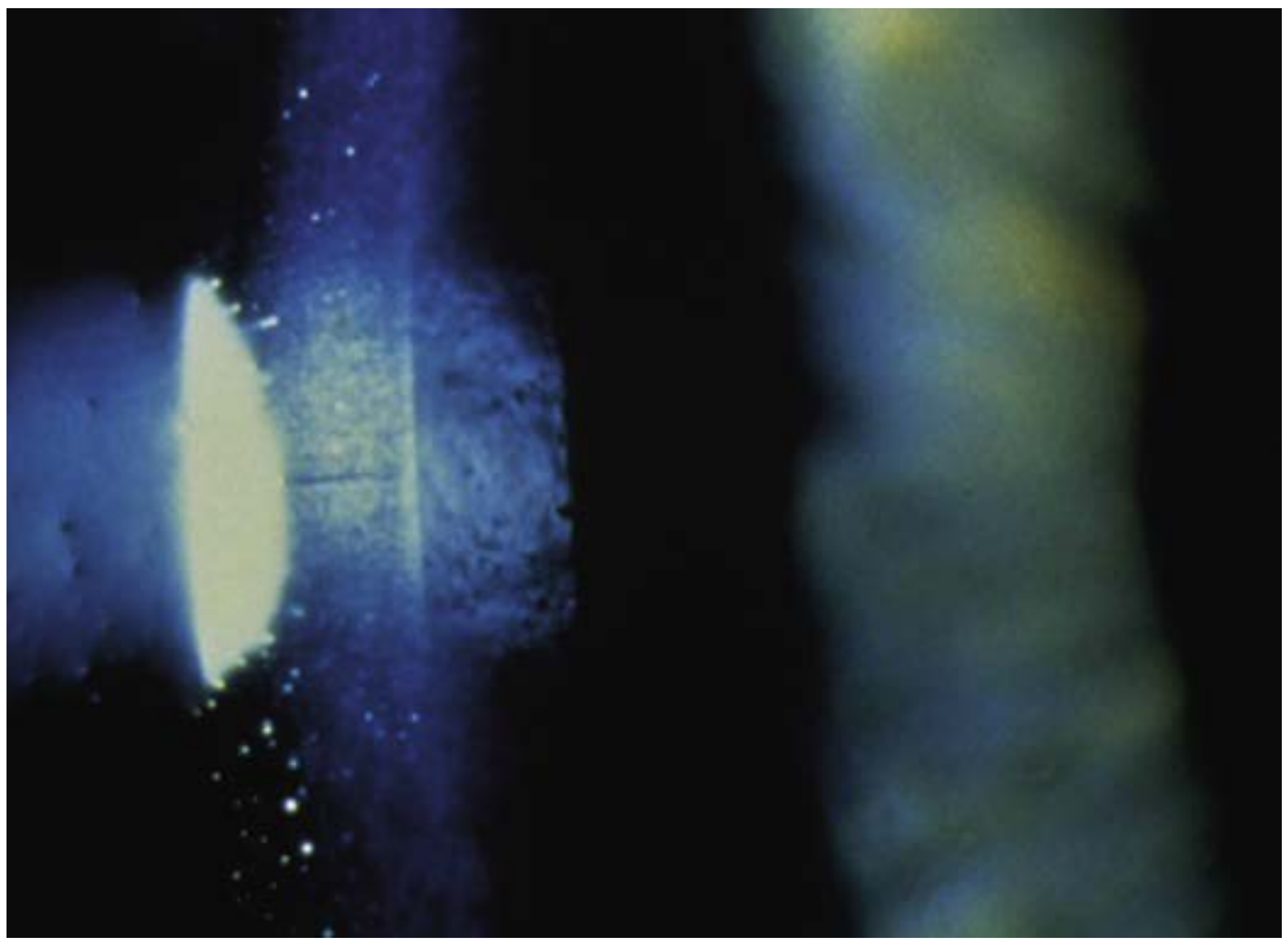

Fig. 40.51 Endothelial blebs can be seen in specular reflection (×40) immediately to the left of the dark band running down the centre of the picture. (Courtesy of Steve Zantos.)

On the assumption that CLEB represents a mild inflammatory uveal response, the origin of the inflammatory cells is likely to be the iris and/or ciliary body. During inflammation, vascular permeability is increased and inflammatory cells leave vessels in the iris and ciliary body and float around in the aqueous until they come to rest on the endothelial surface. One would therefore expect to observe mild aqueous flare occasionally in patients with CLEB, but this does not appear to have been reported. This mild inflammatory status probably causes lens intolerance.

Patient management is guided by symptomatology rather than clinical signs. Wearing time should be reduced to a level that represents the balance between the needs of the patient to wear lenses for a desired length of time each day and the level of discomfort that can be tolerated (McMonnies and Zantos, 1979). The presence of inflammatory cells on the endothelial surface should be viewed with great caution by clinicians, because the condition may not necessarily be related to lens wear. Certainly, all forms of uveitis should be considered and tests should be conducted to exclude such possibilities. In all cases of CLEB, intraocular pressures should be measured because some inflammatory cells may have migrated into the anterior angle, creating a blockage of aqueous outflow. Gonioscopy is also indicated, especially if intraocular pressure is elevated.

The pattern of recovery from CLEB is variable. In some cases bedewing will completely disappear within 4 months, and in other cases it may change little over a much longer time period. Lens intolerance may persist for many months in some patients, even after the bedewing has disappeared (McMonnies and Zantos, 1979).

BLEBS

The endothelial mosaic undergoes a dramatic alteration in appearance in all lens wearers within minutes of inserting a contact lens. These changes can only just be resolved when observed under the highest magnification possible (×40) using the slit-lamp biomicroscope (Fig. 40.51). When viewed at much greater magnification (×200), a number of black, non-reflecting areas can be seen in the endothelial mosaic corresponding to

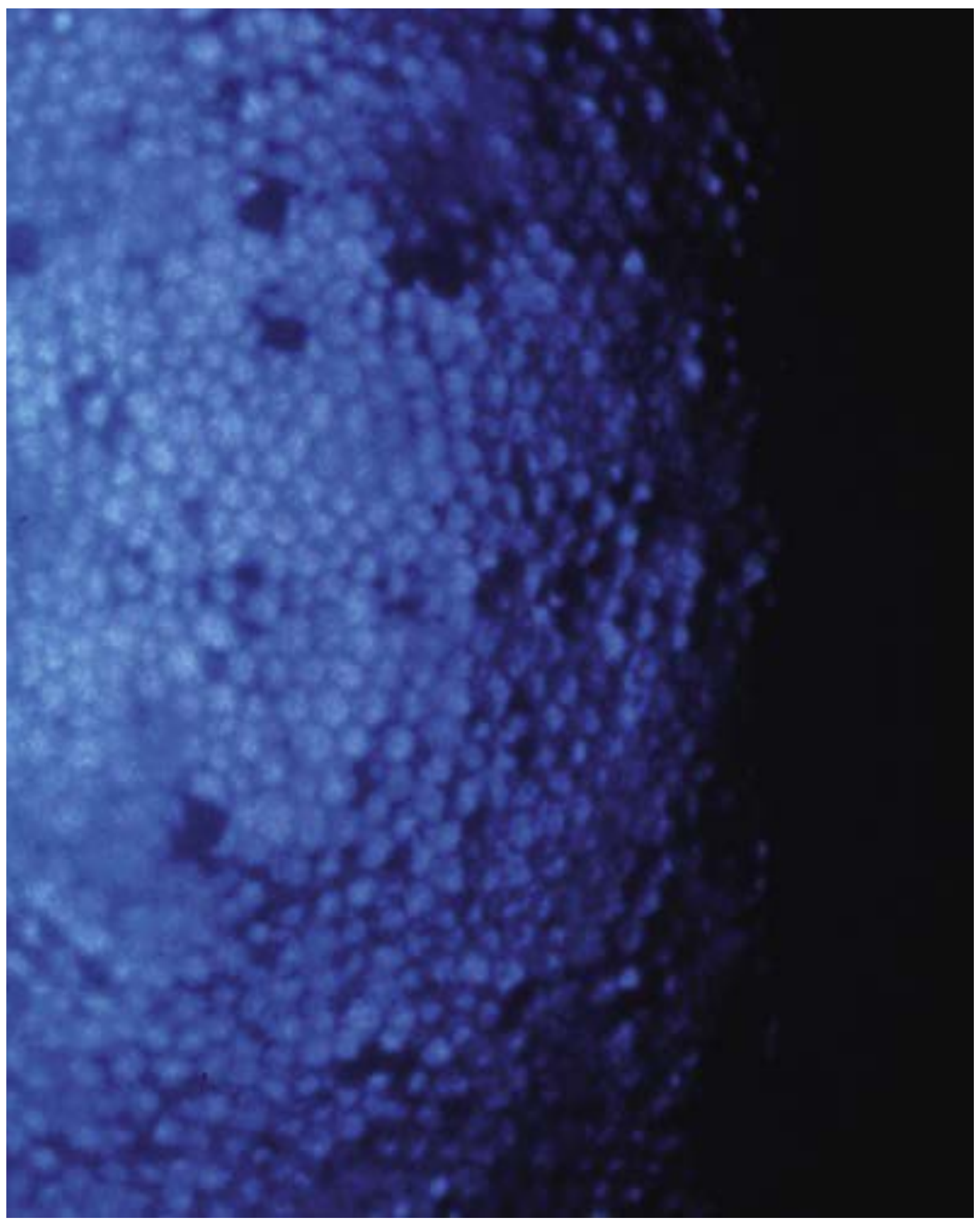

Fig. 40.52 Endothelial blebs viewed at ×200 magnification. (Courtesy of Steve Zantos.)

the position of individual cells or groups of cells (Fig. 40.52). These are called blebs. There is also an apparent increase in the separation between cells (Zantos and Holden, 1977). There is a large variation in the intensity of the response between patients.

Blebs can be seen within 10 minutes of lens insertion. The number of blebs peaks in 20–30 minutes (grade 3), then decreases to a lower level after about 45–60 minutes. A low-level bleb response (grade 1–2) can be observed throughout the remainder of the wearing period. Hydrogel lenses cause a greater bleb response than rigid lenses, and hydrogel lenses of greater average thickness also induce a greater response than thinner lenses. Brennan et al. (2008) demonstrated the percentage area of blebs in response to overnight wear of a 38% water-content hydrogel lens to be 8%, whereas the percentage area of blebs in response to overnight wear of three silicone hydrogel lenses ranged from 1.6 to 2.0%. The percentage area of blebs in response to open-eye wear of silicone hydrogel lenses was 0.4%.

The appearance of blebs can be explained as follows. When the endothelium is viewed using specular reflection, light rays reflect from the tissue plane corresponding to the interface between the posterior surface of the endothelium and the aqueous humour. This interface acts as the reflective surface because it represents a significant change in tissue refractive index. The light rays that are reflected from this interface give rise to an observed image of an essentially flat (or slightly undulating) and featureless endothelial cell mosaic. Light rays that strike 'blebbed' endothelial cells will be deflected away from the observation path, leaving a corresponding area of darkness. Thus, an endothelial bleb is simply an individual endothelial cell (or group of adjacent cells) that has become swollen and bulged in the direction of the aqueous humour, giving rise to the compelling optical illusion that the cell (or cells) has disappeared.

Endothelial blebs are caused by a local acidic pH change at the endothelium. Two separate factors induce an acidic shift in the cornea during contact lens wear: (1) an increase in carbonic acid owing to retardation of carbon dioxide efflux (hypercapnia) by a contact lens; and (2) increased levels of lactic acid as a result of lens-induced oxygen deprivation (hypoxia) and the consequent increase in anaerobic metabolism (Holden et al., 1985b). All cells in the human body function optimally when surrounded by extracellular fluid that is maintained within an acceptable range of pH, temperature, tonicity and ion balance. The carbonic acid and lactic acid alter the physiological status of the environment surrounding the endothelial cells by shifting pH in the acidic direction. This induces changes in membrane permeability and/or membrane pump activity, resulting in a net movement of water into certain endothelial cells when the threshold for a change in membrane permeability is exceeded for those cells. The resultant cellular oedema in such cells is observed as 'blebbing'.

Despite their stunning clinical appearance, blebs are asymptomatic and are thought to be of little clinical significance. After removal of a contact lens, blebs disappear within minutes.

POLYMEGETHISM

The human corneal endothelium is a single-cell layer that appears as an ordered mosaic of primarily hexagonal-shaped cells (Fig. 40.53A). A significant variation in apparent size of cells is referred to as endothelial polymegethism (Fig. 40.53B). ('Polymegethism' is derived from the Greek word megethos meaning 'size'; poly means 'many'). The extent of polymegethism increases throughout life; consequently, the degree of lens-induced polymegethism should be taken to mean the degree of change in excess of that expected for a given age.

It is difficult to assess the integrity of the endothelium using a slit-lamp biomicroscope, because individual endothelial cells are just beyond the limit of resolution. Thus, a normal endothelial mosaic can be seen only as a speckled or textured field. Endothelial polymegethism of a severity greater than grade 2 can sometimes be detected because some of the larger cells can be seen (Fig. 40.54). Inspection of the endothelium is best undertaken using instruments designed specifically for high-magnification imaging, such as the specular endothelial microscope or confocal microscope.

Sweeney (1992) has drawn an anecdotal association between endothelial polymegethism and a condition that she termed 'corneal exhaustion syndrome'. This is a condition in which patients who have worn hydrogel contact lenses for many years suddenly develop a severe intolerance to lens wear characterized by ocular discomfort, reduced vision, photophobia and an excessive oedema response. These patients also displayed a distorted endothelial mosaic and moderate to severe polymegethism. Bergmanson (1992), however, has observed that the endothelium of contact lens wearers showed some inter- and intracellular oedema; the cells were otherwise of a healthy appearance containing normal, undamaged organelles. He argues that endothelial polymegethism is a non-problematic adaptation to chronic metabolic stress.

The suggestion that endothelial polymegethism is a benign tissue change has been challenged by researchers who have demonstrated a link between endothelial polymegethism and corneal hydration control (Nieuwendaal et al., 1994). Recovery from oedema is significantly slower in the corneas of contact lens wearers than in matched controls who have corneas with lower levels of polymegethism.

It is likely that the aetiology of endothelial polymegethism – contact-lens-induced endothelial acidosis – is precisely the same as the aetiology of endothelial blebs, whereby the former represents a chronic response and the latter represents an acute response to the same stimuli. Endothelial acidosis may induce changes in membrane permeability and/or membrane pump

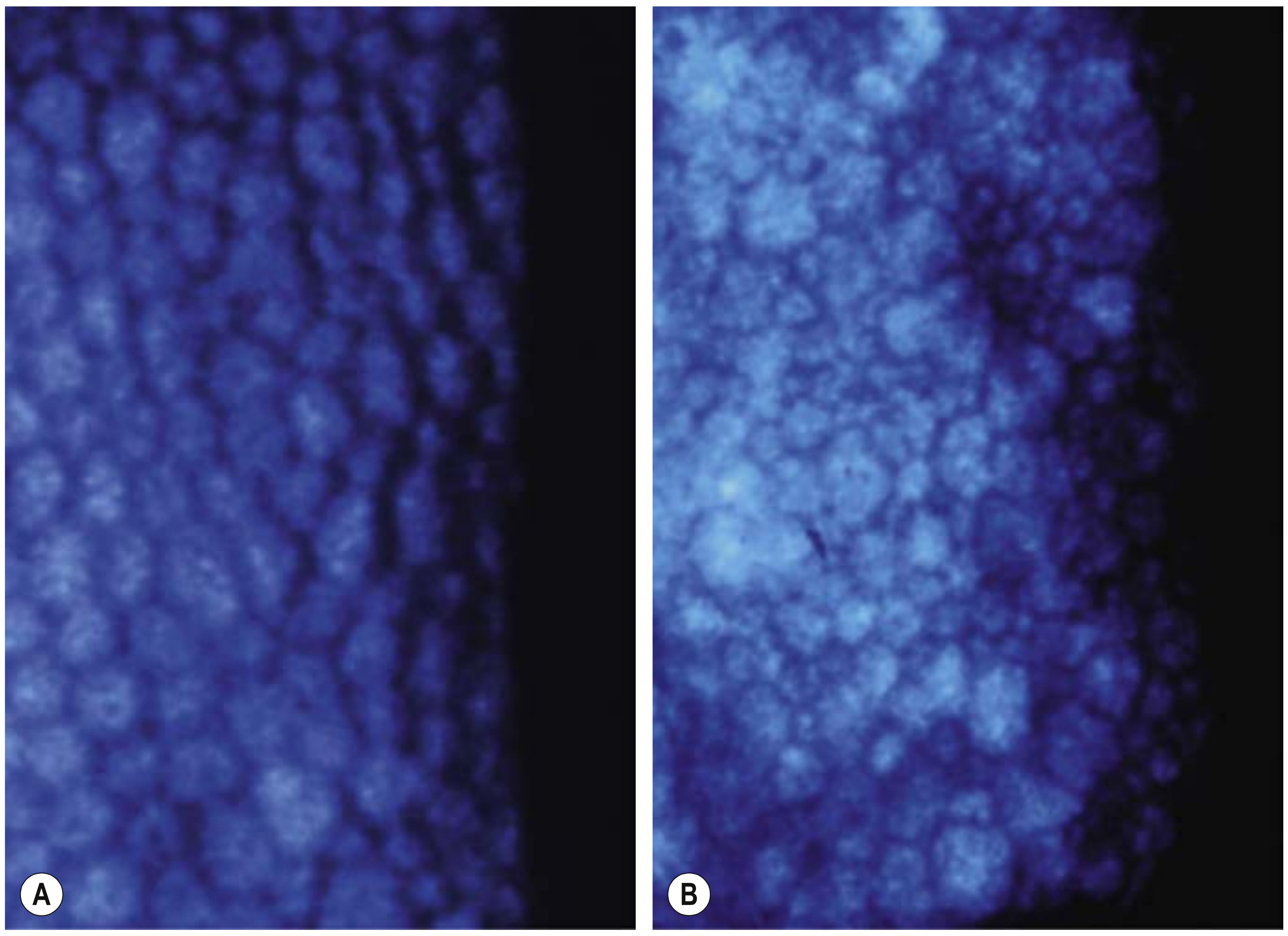

Fig. 40.53 (A) Normal endothelial mosaic. (B) Endothelium displaying severe (grade 3.5) polymegethism. (Courtesy of Steve Zantos.)

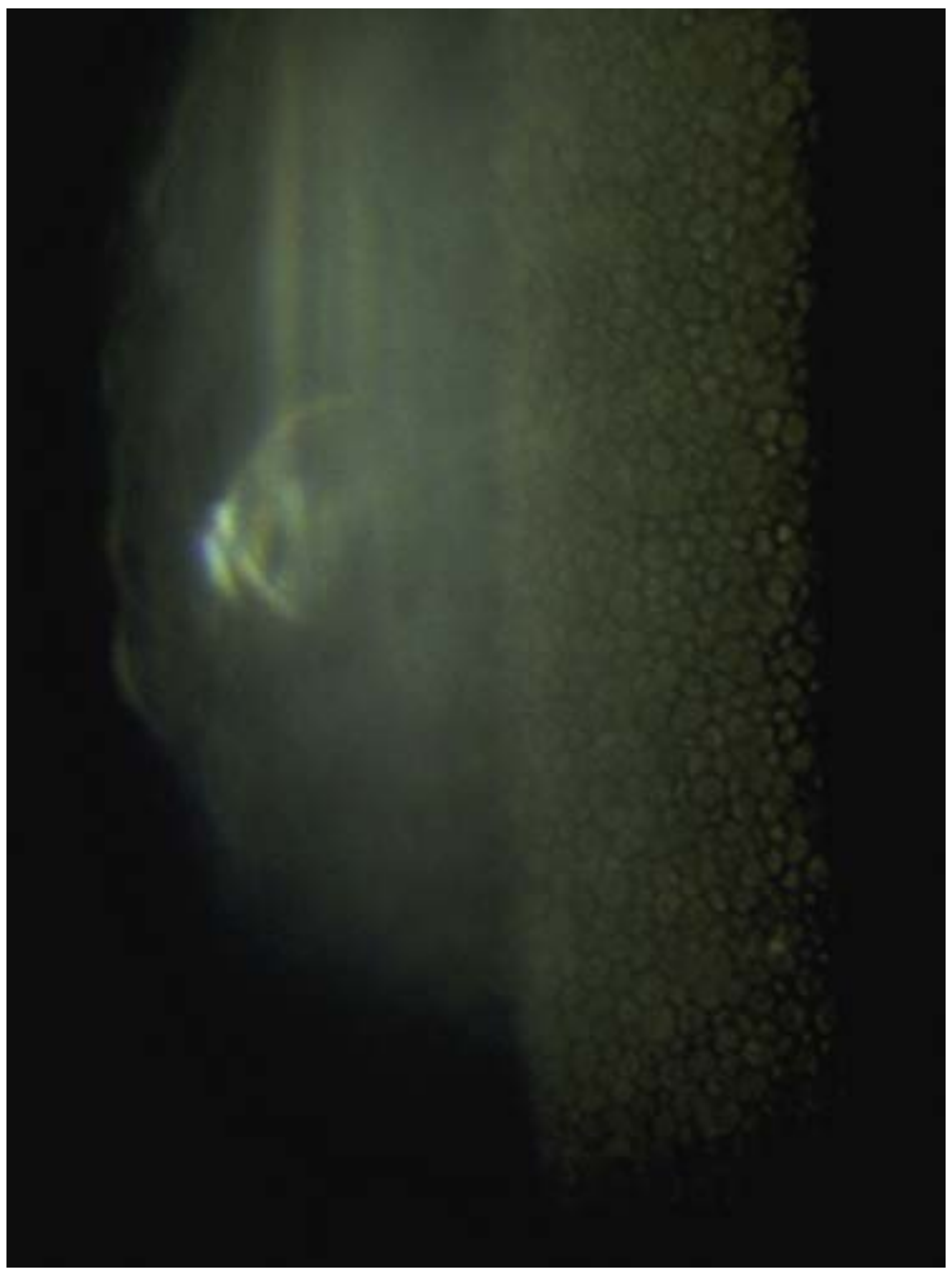

Fig. 40.54 Enlarged view of the endothelium as seen with a slit-lamp biomicroscope, showing polymegethism induced by 10 years of soft contact lens wear. (Courtesy of Rolf Haberer, Bausch & Lomb Slide Library.)

activity, resulting in water movement that acts to elongate endothelial cell walls. A reconfiguration of cell shape then occurs in order to preserve cell volume, resulting in the appearance of polymegethism at the apical surface of the endothelium (Bergmanson, 1992).

Lenses of higher oxygen performance will induce lower levels of polymegethism (Holden et al., 1985a). Doughty et al. (2005) found no significant change in endothelial polymegethism after 6 months of silicone hydrogel lens wear. From a clinical perspective, it is essential to take note of the presence of significant endothelial polymegethism and to take action to minimize the metabolic stress to the cornea known to be associated with this change.

Strategies for alleviating contact-lens-induced hypoxia and hypercapnia include the following:

- fitting lenses of higher oxygen transmissibility, such as silicone hydrogel lenses
- sleeping in extended-wear lenses less frequently
- changing from extended lens wear to daily lens wear
- reducing lens-wearing time
- fitting rigid lenses with more movement and edge lift (to enhance oxygen-enriching tear exchange).

The prognosis for recovery from endothelial polymegethism is poor. Holden et al. (1985c) were unable to detect a recovery from endothelial polymegethism 6 months after removal and cessation of wear of high-water-content hydrogel contact lenses that had previously been worn on an extended-wear basis for an average of 5 years.

Conclusion

This chapter has provided key clinical insights into some of the more common contact lens complications. Many other rare conditions and interesting variations of the complications discussed above have not been considered. The reader is therefore directed to textbooks devoted exclusively to this subject for more detailed information, and encouraged to monitor the ophthalmic literature constantly. As more sophisticated tools continue to be developed that can be used to study the ocular response of the living eye to contact lens wear – such as confocal microscopy and optical coherence tomography (see Chapter 36) – it is certain that further tissue reactions and complications will continue to be revealed.

Access the complete references list online at http://www.expertconsult.com.

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41

Digital Imaging

ADRIAN S BRUCE | MILTON M HOM

Introduction

Digital imaging can be a valuable component of contact lens practice (Fig. 41.1). The term refers to the electronic capture and display of an image, by using a combination of computer and camera. In contact lens practice, digital imaging is most often used to document contact lens fittings and ocular pathology. As with all forms of technology, the cameras and computer systems continue to become better in quality, less expensive to set up and easier to operate.

Advances in imaging for eye care are truly remarkable. The advances in smartphones have changed the landscape. Earlier photo systems used 35 mm film-based cameras and required a slit lamp with a built-in flash tube. A video camera mounted on a slit lamp was also used for imaging, student teaching and patient educations (Hammack, 1995).

However, the most common method for recording contact lens fittings or ocular changes remains the use of handwritten (or electronic) notes and diagrams. In recent years these have been improved with the advent of formal grading scales (Efron et al., 2001; Pritchard et al., 2003) (see Chapter 39 and Appendix K).

This chapter outlines the benefits of digital imaging for contact lens practice, shows the results that can be obtained and illustrates a number of available systems.

Benefits of Digital Imaging for Contact Lens Practice

There are numerous features and benefits with digital imaging (Bruce, 2012). These include the following:

- Instant imaging – the record is simply and instantly made. The magnification and lighting may be varied in real time to improve image quality.
- Minimal image costs – once a digital imaging system is set up, the unit cost for each image is virtually zero. With modern computers having multigigabyte hard-disk capacity, many thousands of images may be easily stored and retrieved.
- Image manipulation and quantification – after an image is captured, the brightness, contrast or colour may be enhanced (see below). Furthermore, image parameters can be quantified by the computer (e.g. blood vessel length, scar dimensions and cup / disc ratio). However, care must be taken not to alter an image that may be legal evidence.
- Video movies – dynamic conditions such as contact lens fittings or certain dynamic forms of pathology evaluation can be captured as a short movie on the computer. Lens performance is much easier to understand and interpret when a moving (versus static) image is presented.
- Portability and accessibility– images can be easily transferred and viewed on smartphones. Some patients love to post their images on social media sites like Facebook or Instagram.

Once the digital image has been captured in an electronic format; this opens up the following possibilities:

- Better patient care – one problem with notes and diagrams is variability between observers. Even within the same observer, over a long interval between visits some interpretation of the notes may be required. Photodocumentation is valuable to evaluate progression or healing in the patient's condition.
- Patient education – there is a benefit in the patient immediately seeing his / her own condition. The patient 'wow' factor is beneficial to practice growth – perhaps the biggest pay-off from imaging (Schwartz, 1998).
- Paperless office – many contact lens practices are using electronic medical records for patient visits. Digital imaging is a logical adjunct to electronic records and has great value in cases of potential legal action (Schwartz, 1998). With the internet, patient records can be accessed at more than one office location.
- Image transfer – increasingly, clinicians are communicating by email. A digital image is already on the computer and this makes attachment to an email easy. E-mail has made consultations with colleagues from all over the world accessible.
- Presentations – images can be transferred to computer presentation programs, which are used for presentations and teaching purposes. Digital images can easily be dropped into PowerPoint and Keynote presentation programs.

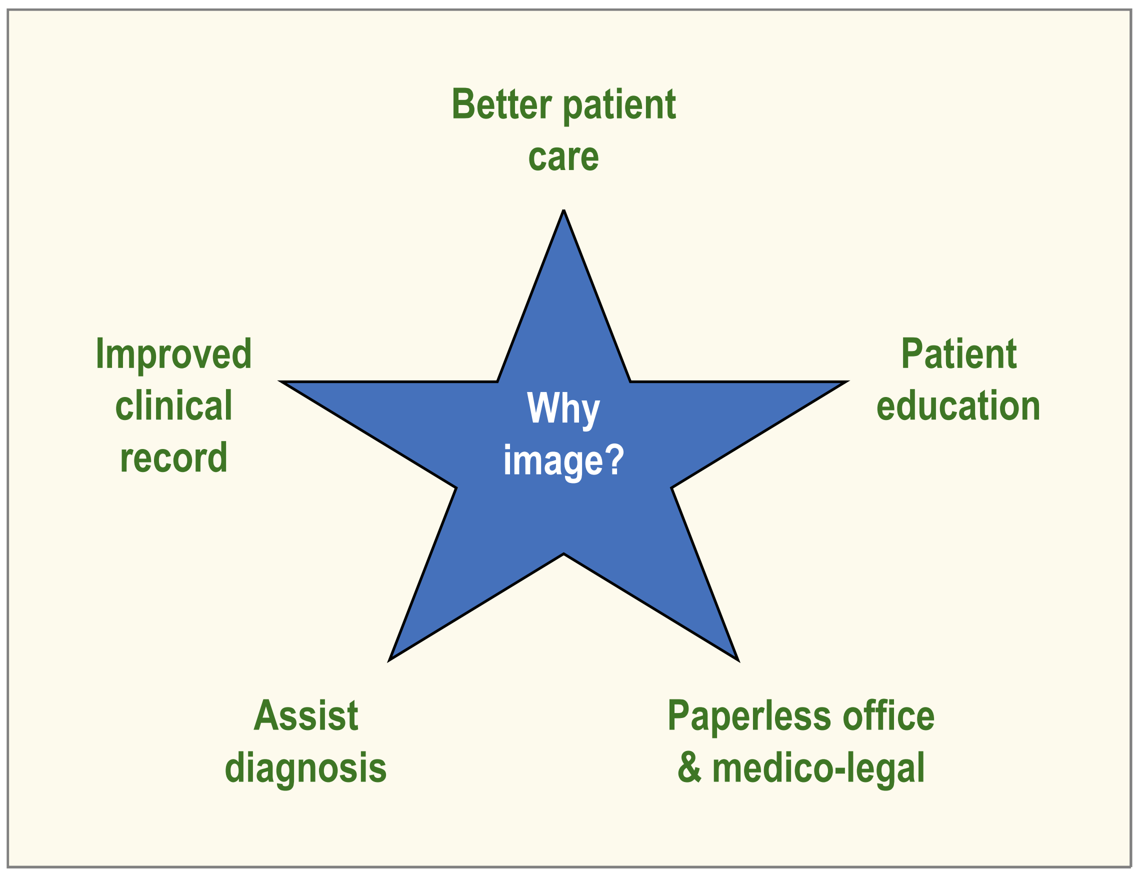


Fig. 41.1 Why digital image? Digital cameras are very accessible, electronic records have become a key driver, and patient quality of care can be enhanced.

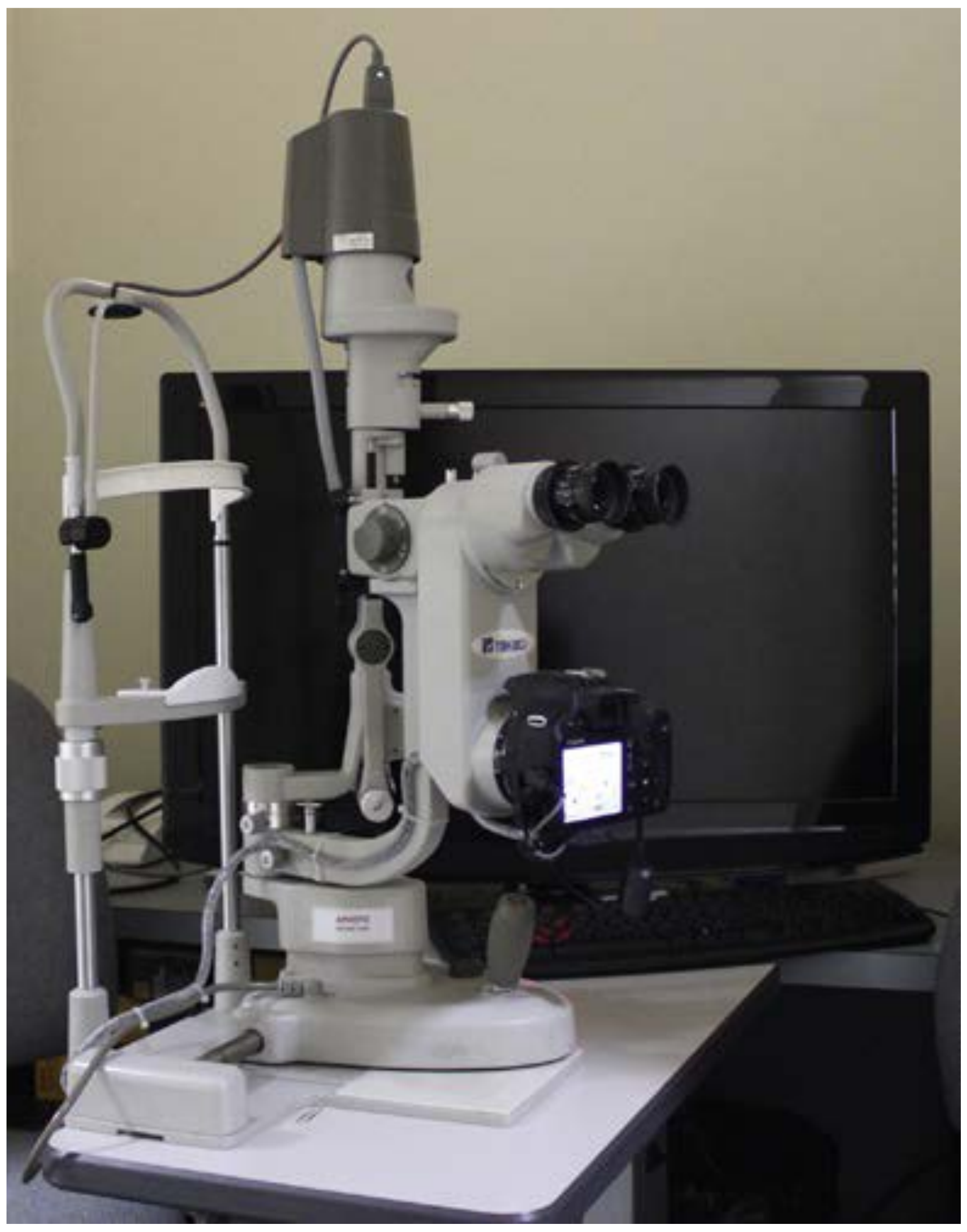


Fig. 41.2 Digital SLR camera system. A Takagi SM-70N slit-lamp microscope (Takagi-Seiko Co., Nagano-Ken, Japan), with a digital camera adaptor (TD-2A) and Canon EOS 500D 15 megapixel camera (Canon Inc., Tokyo, Japan). The camera default settings are ISO 1600 speed with 1/15th second exposure. (Courtesy of Takagi-Seiko Co. and Canon Inc.)

In summary, photodocumentation enhances communication with patients as well as enhancing the quality of clinical records. With the increased use of electronic medical records, hand-drawing is reduced, making digital imaging more necessary (Sanders et al., 2013). The merits of photodocumentation are numerous. Digital imaging has taken clinical documentation to another level.

How much Resolution is Required for Anterior Eye Digital Imaging?

The basic principle of digital imaging is that a light-sensitive silicon computer chip is used in a camera. The silicon chip is known as a charge-coupled device (CCD), and the number of light-sensitive elements on the CCD determines the image resolution for video and digital cameras. The two most common types of camera used for digital imaging are the smartphone and the digital SLR (Fig. 41.2). Modern smartphone cameras can take good quality moderate-resolution images through the eyepiece of a slit lamp with high illumination (Fig. 41.3).

Previous reviews of digital imaging have discussed the issues of image formats and colour depth (Peterson and Wolffsohn, 2005; Wolffsohn and Peterson, 2006) and these are therefore not covered in great depth here. Some common clinical issues are discussed below.

The image resolution refers to the image dimensions (width × height) in units of the number of dots (pixels). As the image proportions for most cameras are in a 4:3 aspect ratio, the resolutions are simply referred to as a million pixel count (e.g. 10 megapixels).

One way to consider this question of 'how much resolution' is by the unit of detail that needs to be recorded. Fig. 41.4 shows a number of clinical signs that an ideal digital imaging system should be able to capture. Examples are: (A) corneal punctate staining, (B) keratic precipitates, (C) endothelial cells and (D) epicapsular stars.

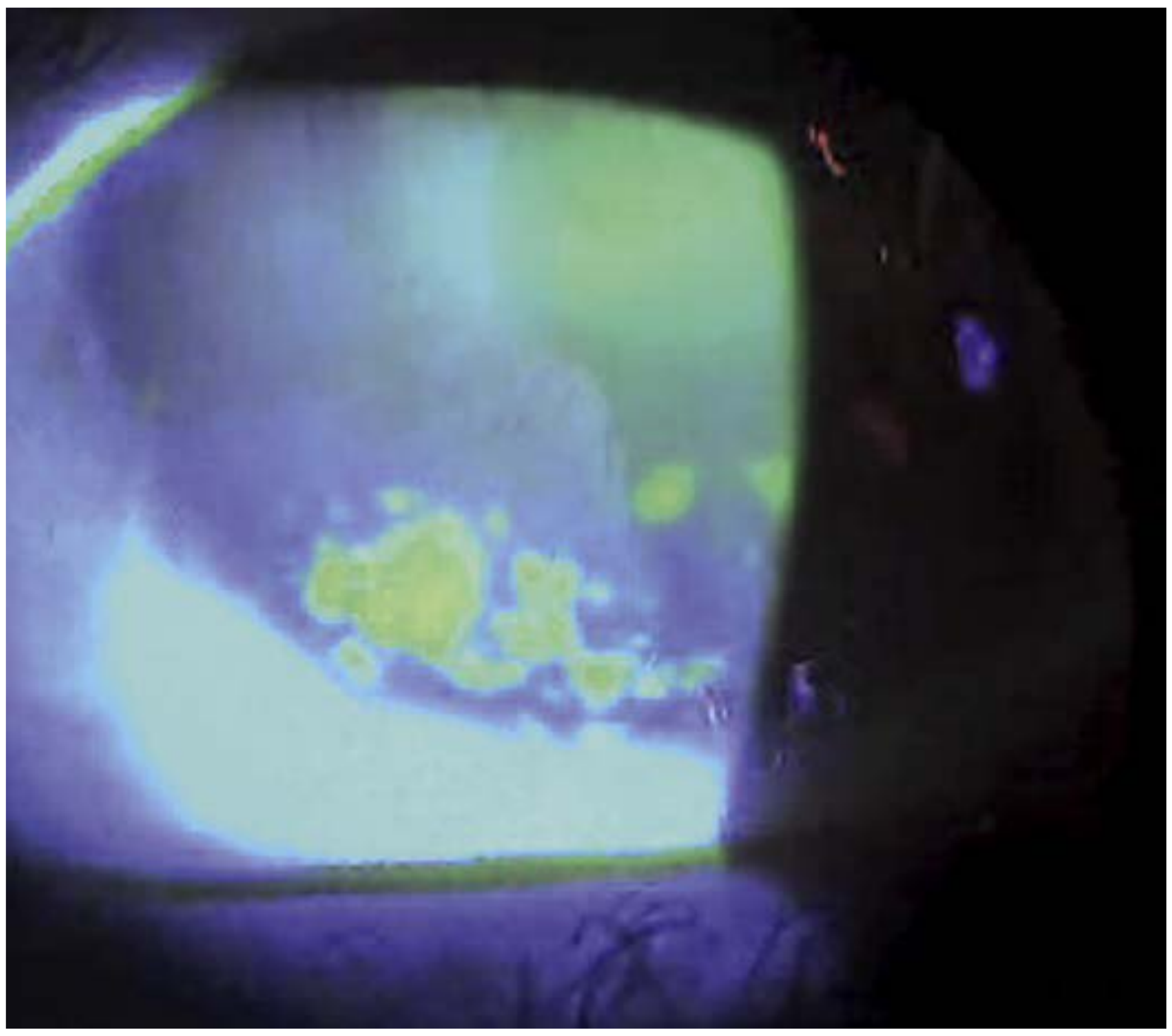


Fig. 41.3 Image of corneal staining taken through the eyepiece of a slit lamp, with a smartphone. Such digital imaging is highly accessible and convenient, although the quality may be limited.

These features are 20–50 µm in size and if the digital imaging system can surpass this resolution by a factor of 10 (i.e. 2–5 µm) then the characteristics of each feature should be discernible in the final image. A 15 megapixel camera on a slit lamp with 16× magnification should give this resolution (i.e. 3 µm). Ye et al. (2013) measured the spatial resolution of a commercial slit lamp with a single lens reflex (SLR) camera to be near 2 µm, although they commented that the spatial resolution apparent to the observer was higher still.

How do I get a Brighter Image?

There are four commonly used illumination techniques for photodocumentation:

1. Diffuser – this is best for opaque tissues, such as the conjunctiva, sclera and eyelids. It is used in conjunction with a full-width slit, and the brightness of the beam is varied for optimum exposure.
2. Slit section – this is most useful for transparent tissues. An angled slit beam gives a dark-field background to highlight features. A slit section can also be used with retroillumination so as to highlight opaque tissue changes.
3. Fluorescein staining – surface defects are best shown with the combination of a cobalt blue illumination filter and a yellow barrier filter with a wide slit beam.
4. Tear film assessment – specular illumination with the slit lamp or other instrument will show lipid layer patterns, tear film thickness and break-up (Nichols et al., 2002).

Underexposure of anterior eye digital images is a common problem. The camera needs to have good low-light performance in order to obtain high-contrast slit images or to show fluorescein staining with filters in place. Smartphone cameras are usually fully automatic, so all you can do is have the slit lamp on a high light level and use a low magnification on the biomicroscope. A low magnification gives a larger exit pupil for the biomicroscope optics, so more light will enter the camera. Where possible, turn off the smartphone flash and autofocus. For a modern digital SLR camera, apply the manual settings (e.g. a high ISO

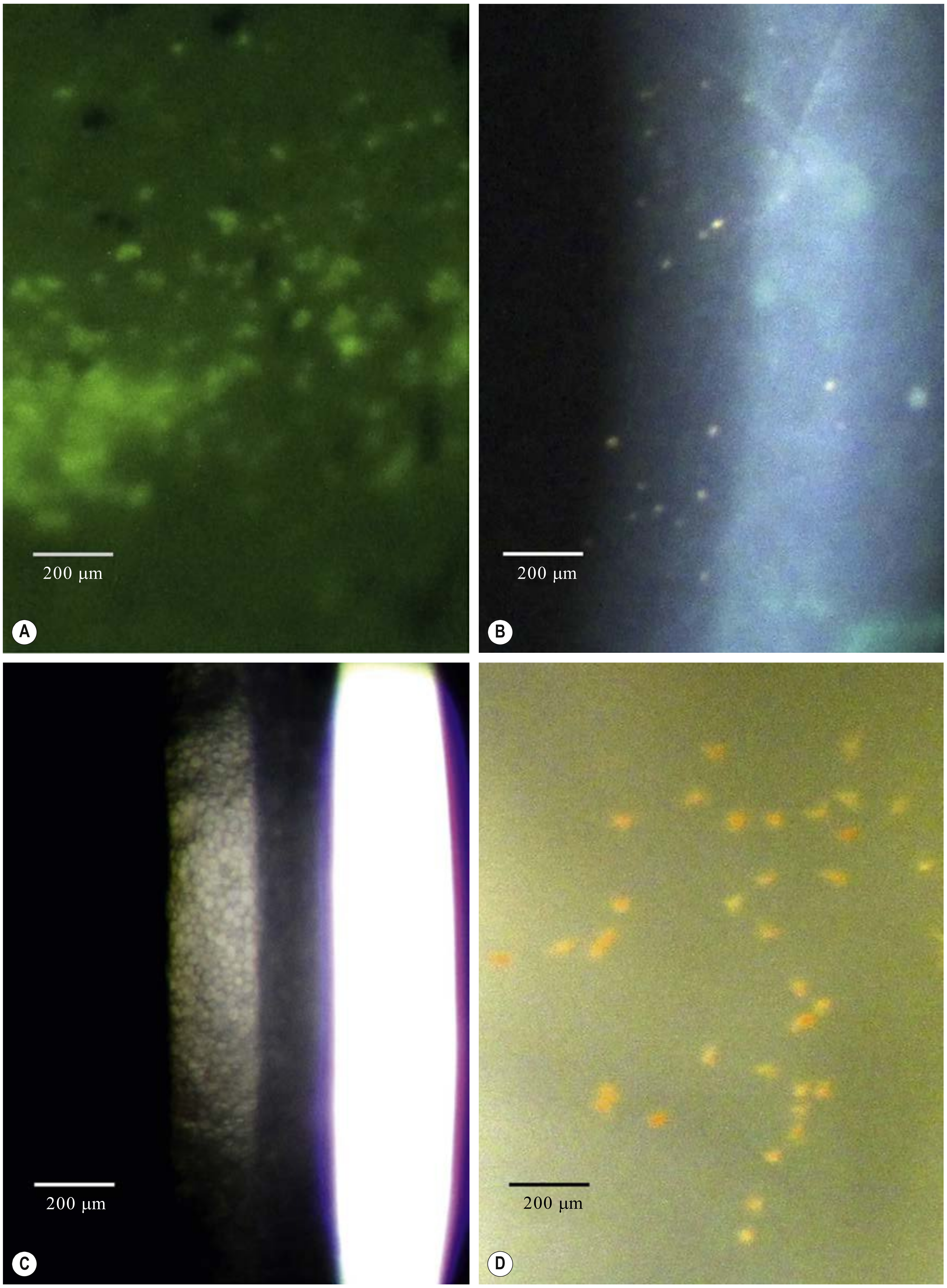


Fig. 41.4 How much resolution is required for anterior eye digital imaging? Examples of cellular-scale detail visible with slitlamp digital imaging. (A) corneal punctate staining, (B) keratic precipitates, (C) endothelial cells and (D) epicapsular stars. These features are 20–50 µm in size and if the digital imaging system can surpass this resolution by a factor of 10 (i.e. 2–5 µm) then the characteristics of each feature should be discernible in the final image.

speed of 1600 or more and a slower shutter speed of 1 / 15th to 1 / 25th second). Excellent results can be obtained with a digital SLR camera. A full-featured digital slit lamp has a flash system built in to the illumination path; however, such slit lamps carry a higher cost and are more complex.

Examples of digital images for each of the illumination types are shown in Fig. 41.5. The corneal optic section is particularly useful in assessing corneal ectasia and corneal transplant (graft) condition. The contour of the corneal profile and variations in the corneal layers or lamellae are critical signs in terms of the

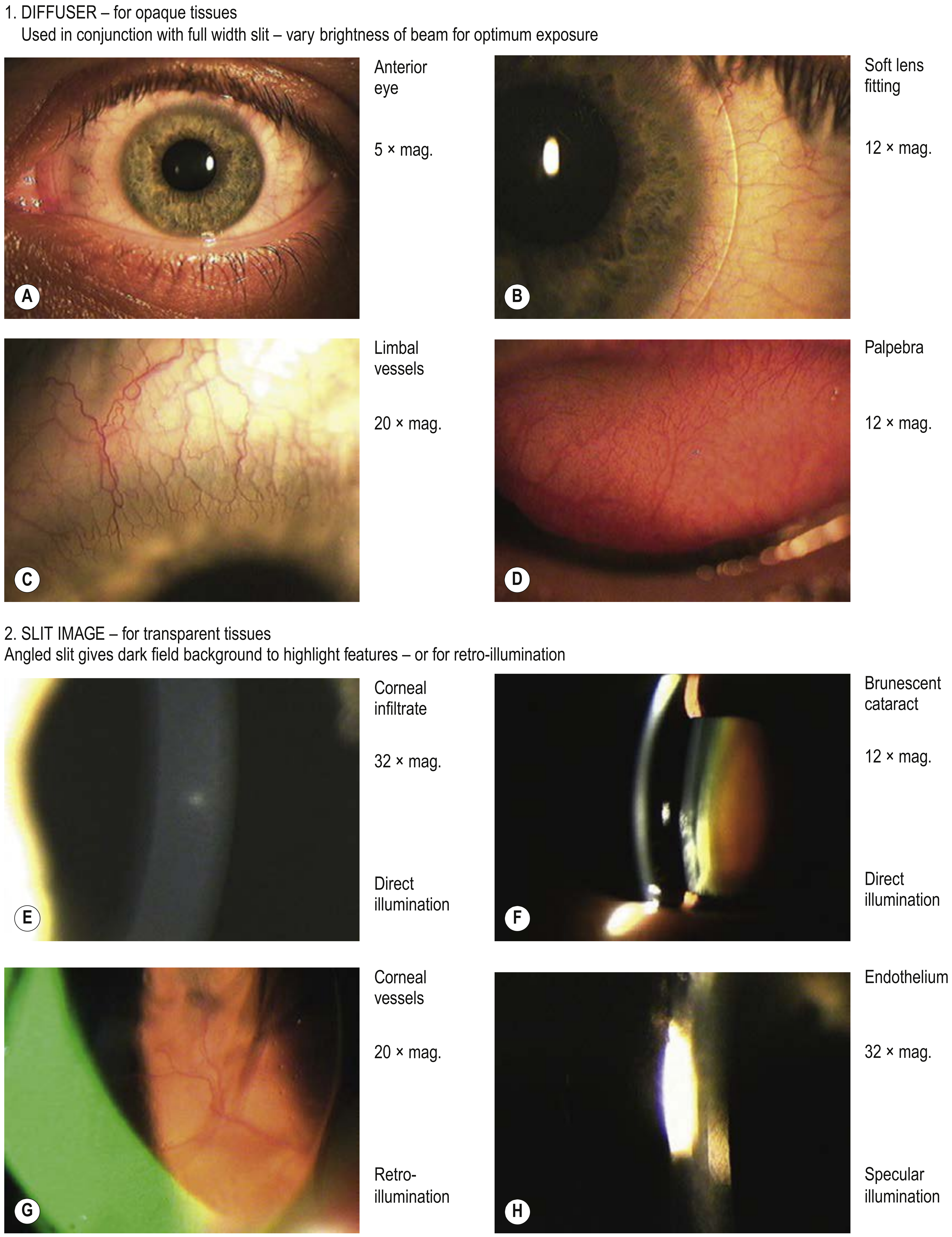

1. DIFFUSER – for opaque tissues
Used in conjunction with full width slit – vary brightness of beam for optimum exposure
Anterior eye
5 × mag.
A
Soft lens fitting
12 × mag.
B
Limbal vessels
20 × mag.
C
Palpebra
12 × mag.
D
2. SLIT IMAGE – for transparent tissues
Angled slit gives dark field background to highlight features – or for retro-illumination
Corneal infiltrate
32 × mag.
Direct illumination
E
Brunescent cataract
12 × mag.
Direct illumination
F
Corneal vessels
20 × mag.
Retro-illumination
G
Endothelium
32 × mag.
Specular illumination
H

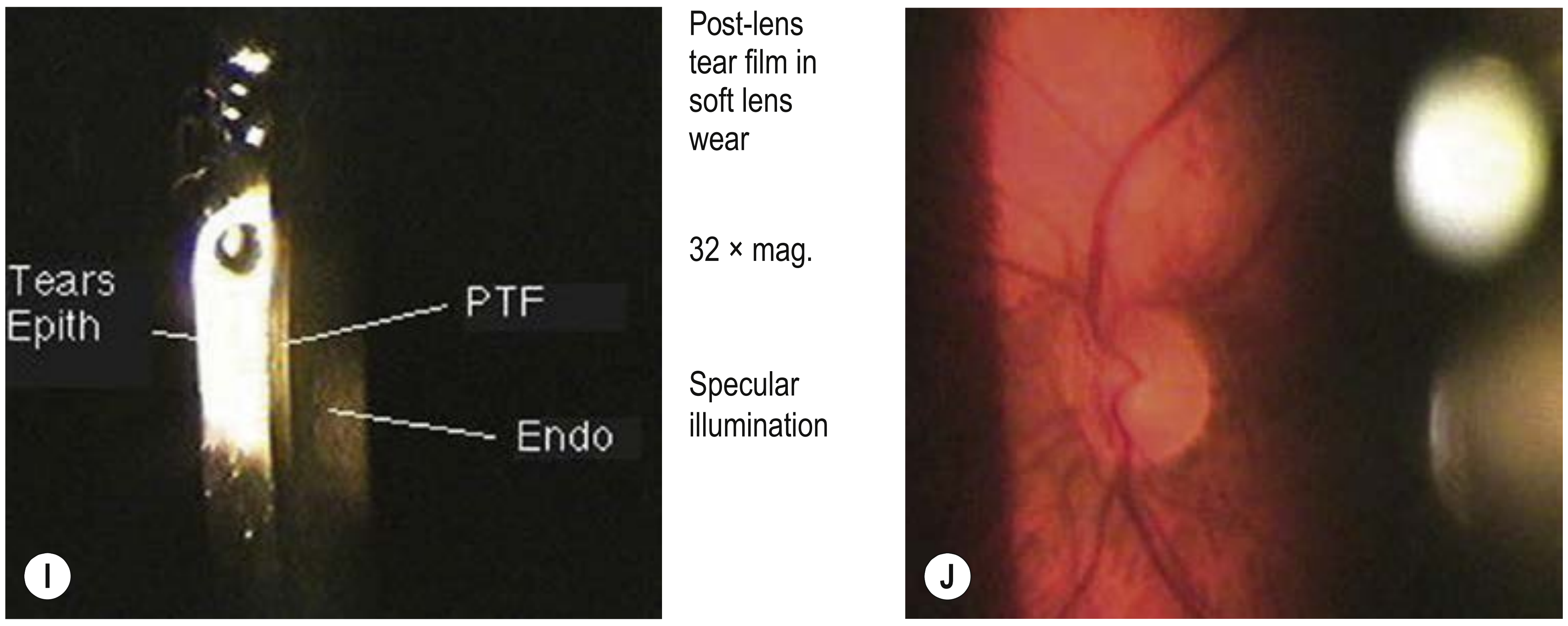
Fig. 41.5 Slit-lamp photography: illumination and magnification guide.

patient's vision and indications in terms of work-ups and management plans. By looking at the centre of the cornea, but having the light beam at an oblique angle of 30–40°, the corneal shape profile, thickness and layers may be assessed (Fig. 41.6).

Commercial Digital Imaging Systems

Contact lens practitioners wishing to enter the world of digital imaging have the choice of purchasing a commercially produced system or getting started using a smartphone. A commercially produced digital imaging system can be defined as a ready-to-use integrated system, sold by an ophthalmic equipment supplier. It will typically consist of a slit-lamp biomicroscope attached to a video camera or digital still camera, and a personal computer with database and image manipulation software.

A commercial digital imaging system is probably the best alternative for practitioners who are not so familiar with computers. These systems have the benefit of a relatively simple interface and an easy-to-use database for managing records. The company supplying the equipment will have taken care of the technical issues related to setting up image acquisition by the computer from the video camera.



Post-lens tear film in soft lens wear

32 × mag.

Specular illumination

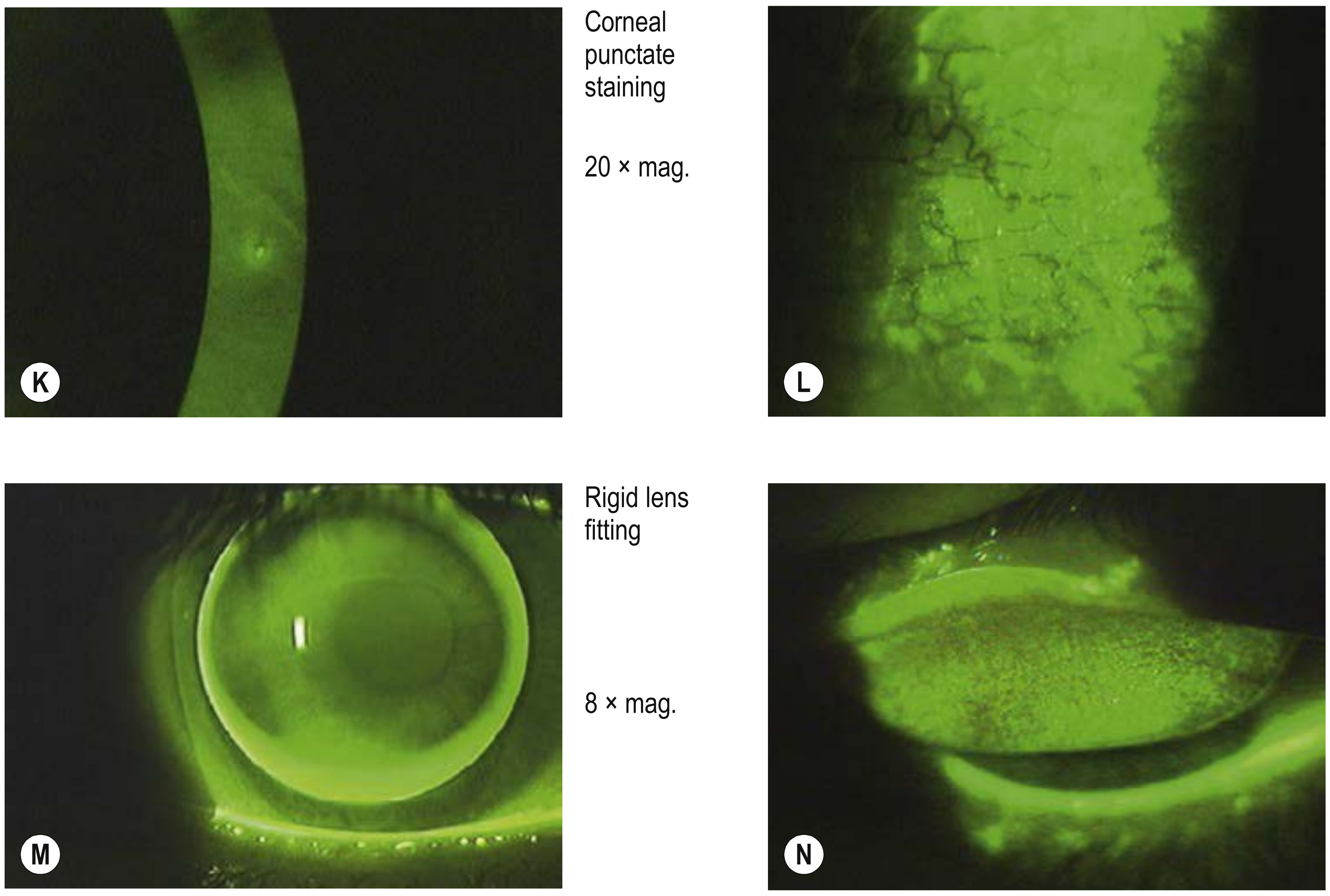
Optic disc viewed with 78 D lens

12 × mag.

Direct illumination

3. FLUORESCEIN STAINING

Cobalt blue illumination filter, yellow barrier filter, high slit brightness; wide slit width



Corneal punctate staining

20 × mag.

Bulbar conjunctival staining

20 × mag.

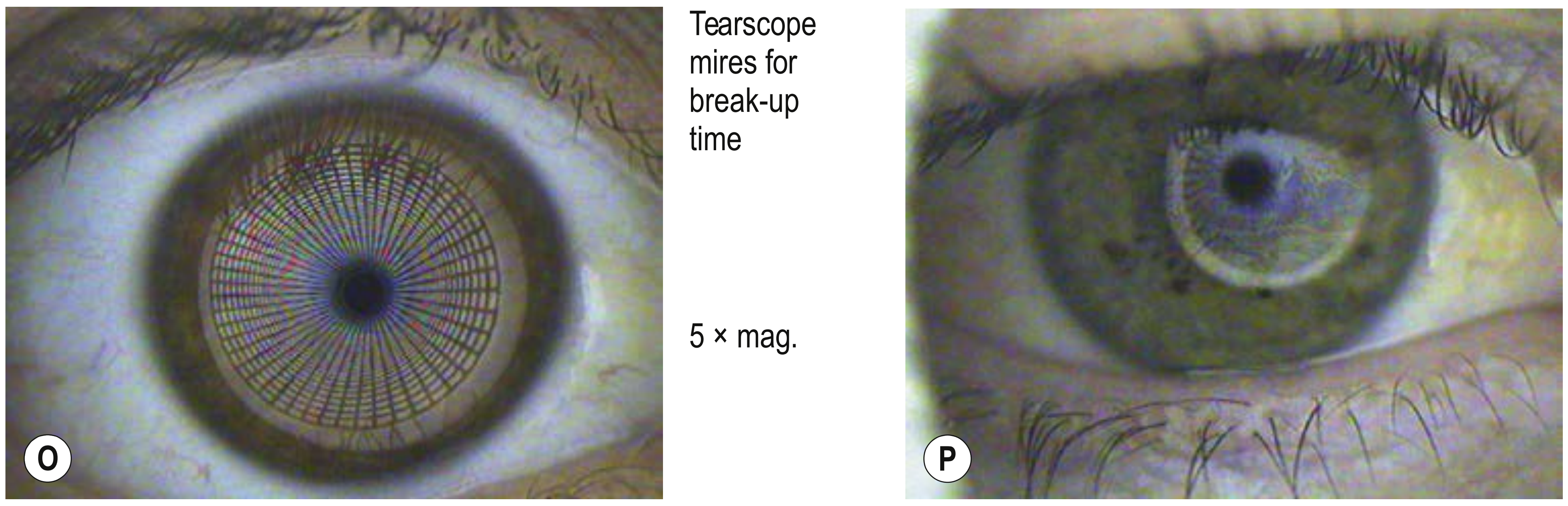
Rigid lens fitting

8 × mag.

Palpebral conjunctiva – early papillary conjunctivitis

5 × mag.

4. TEAR-FILM OBSERVATION WITH THE KEELER TEARSCOPE



Tearscope mires for break-up time

5 × mag.

Lipid layer of tear film, located in a different focal plane to the Tearscope mires

5 × mag.

Fig. 41.5, cont'd (I–P)

Digital SLR Camera Slit-lamp Imaging System

The advantage of a digital still camera is in the high quality and resolution of the image. Professional digital SLR cameras afford high resolution (15 million pixels or more), good low-light performance and options for attaching to instruments. For example, the Takagi slit-lamp biomicroscope (Takagi-Seiko Co., Nagano-Ken, Japan) can be attached to a Canon EOS 500D camera (Canon Inc., Tokyo, Japan) or a camera of equivalent specification. Other features of the system include the following:

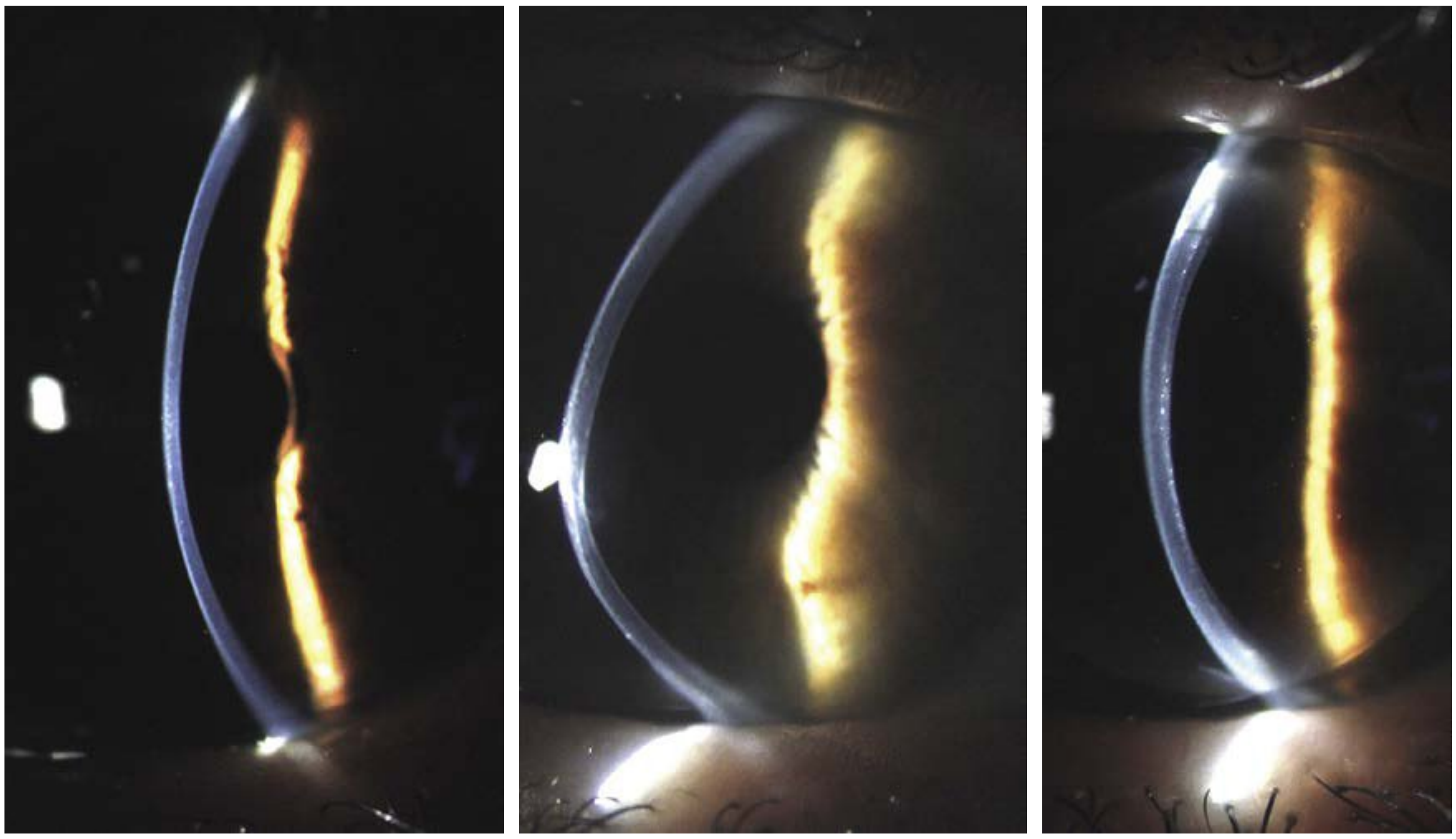


Fig. 41.6 Diagnostic use of corneal optic section at 30–40° incidence. The central image shows corneal ectasia with inferior cone; the left image is normal corneal contour and the right image is a posterior lamellar corneal graft.

1. The digital camera adaptor (TD-2A) includes a yellow written filter to give high-contrast fluorescein images of staining or lens fittings.
2. The digital camera adaptor places the camera away from the binocular eyepieces, to avoid interference with stereo viewing by the observer.
3. The slit lamp has an integrated trigger button included on top of the joystick. In this way, photos are taken with the maximum of convenience in normal slit-lamp operation.
4. An accompanying computer is connected via a USB cable, so that the images taken are instantly viewed and saved. The computer may be directly interfaced with the practice computer program, for integration of file access and connection to the patient record.
5. A separate background fibreoptic illuminator is included for broad illumination of the ocular and preocular tissues.

A commercial digital imaging slit lamp with a SLR camera has the highest image spatial resolution compared with other slit-lamp imaging methods (Ye et al., 2013). Yuan et al., (2015) found the spatial resolution of a Nikon FS-2 slit lamp connected to a Canon 60D digital SLR camera (18 megapixel) was comparable with ultra-high-resolution optical coherence tomography (UHR-OCT), but for a fraction of the cost.

Smartphone Digital Imaging

Perhaps the best reason to consider using your smartphone for digital imaging is the ease of getting started, the low entry cost and the portability – a fraction of the price of a commercial system. Assuming you already have a smartphone (iPhone, Android, etc.), the only cost is an eyepiece adaptor, which is available for a few hundred dollars. You can find out more online about the eyepiece adaptor. If you search YouTube (www.youtube.com) for 'smartphone slit lamp' you will find many guides on how to use such adaptors and where to purchase. A useful online article demonstrating implementation is available at www.journalmtm.com/2014/diy-smartphone-slit-lamp-adaptor/.

As with any digital imaging system, there is a learning curve towards taking good quality images. Where possible, turn off the smartphone flash and autofocus. Initially the best images will be most readily taken using a uniform illumination of the eye – that is, with a broad beam or diffuser in front of the light beam (see Fig. 41.5). Opaque tissues such as eyelids, conjunctiva / sclera or iris should be straightforward. Lower-light imaging such as with fluorescein filters, narrow optic section beam or higher magnifications may take more time. Images can be transferred from the phone to the practice computer system, usually using wireless 'drop boxes' online or email. There is also potential for global telemedicine using a smartphone for real-time slit-lamp eye examination (Ye et al., 2014).

Additional digital imaging applications for smartphones are also being described. It is possible to quantify pupillary anisocoria using a smartphone as a macro-camera (Mojumder et al., 2015). It is also possible to use a smartphone for imaging through a desktop microscope (Skandarajah et al., 2014). Clinical applications of microscopy include assessment of ocular pathogens such as Demodex (Hom et al., 2013).

Video Slit-lamp Imaging System

A video slit lamp may be a relatively low-cost method to capture an image, for display on a screen or to input into a computer. It has the advantage over the smartphone method of being a permanent installation, but has a lower resolution and quality than a digital SLR camera.

The two key steps are to connect a video camera to the slit lamp and to input the video signal into the computer. The permanent connection of a video camera to a slit lamp requires a beam splitter in the slit-lamp observation system.

Some slit lamps, like the Haag-Streit BD900 (Haag-Streit AG, Koeniz, Switzerland), have a standard built-in beam splitter.

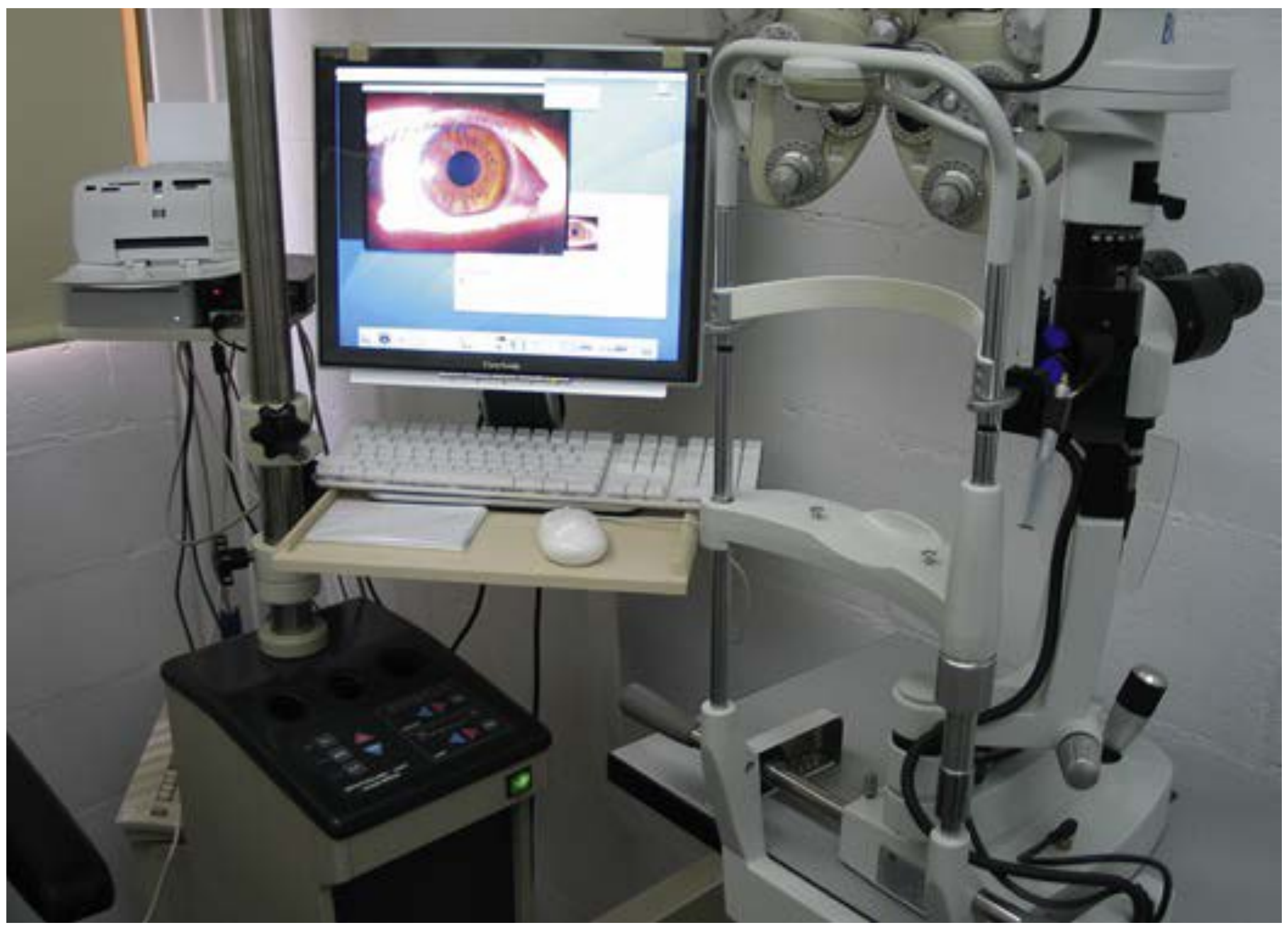


Fig. 41.7 Haag-Streit BD900 video slit lamp, with compact imaging system. (Courtesy of Haag-Streit.)

This is a neat design, since it is in line with the observation system and makes it easy to connect a video (CCD) camera (Fig. 41.7). Other slit lamps, such as the Zeiss SL120 or CSO SL990, have a modular design and the beam splitter and camera can be readily added together. For other slit lamps, it may be necessary to check with the slit-lamp supplier as to whether a suitable beam splitter is available.

For these types of beam splitter, a video camera must be selected. A good solution is a single- or three-CCD microcamera with separate power supply. These are known as 'lipstick' cameras, owing to their compact size, making them suitable for an ophthalmic instrument. The low-light performance, resolution and colour rendering are acceptable for most slit-lamp applications. If a video camera with a digital (Firewire or USB) output is selected, then it will connect directly to the computer. The image can then be displayed on the computer, saved or printed. This option has the benefits of good low-light performance, live image preview and the facility for digital movie capture.

Recording Digital Movies

Contact lens practice is photogenic not only for still images, but also for dynamic movies. Two important uses for movies include recording the dynamic procedures involved in lens fittings, and showing corneal complications as the light source is moved or scanned. Viewing of fluorescein patterns, lens centration and movement benefits immensely from the use of digital movies. Other interesting non-contact-lens-related pathology where motion is useful includes anomalies of the pupils, eye movements and vitreous. Most smartphones and digital SLR cameras have included software to allow movie recording.

File Back-up and Printing

Whatever system is used, it is vital to have a means of backing up the data stored on the slit-lamp-interfaced computer, for example by using a recordable CD-RW or DVD-RW, a removable USB hard disk or a flash memory drive. Recently, the costs of external hard-drive systems have become very reasonable. Attaching an external several-terabyte drive is convenient and easy to do. Backing up to the cloud is also becoming increasingly common; this usually requires an internet connection and adequate storage space.

There is a wide range of printers available, each with its unique benefits. For contact lens private practice work, an inkjet printer is appealing because of its compact size, low capital cost and high-quality prints. If quarter-page (postcard) size images are made for attachment to record cards or referral letters, then both the speed and cost per print are moderate.

Infrared Imaging

The Oculus Keratograph 5M (www.oculus.de) is a unique multifunctional corneal topography and digital imaging instrument. It includes white diode illumination for imaging tear film dynamics, blue diodes for fluorescein images and infrared diodes for meibography of the eyelids. Apart from slit imaging for optic section viewing, it can perform most of the functions of a standard digital imaging camera, with the addition of Placido corneal topography, pupillometry and infrared assessment of the tear film (Fig. 41.8) and meibomian glands (Fig. 41.9). Srinivasan et al. (2012) have suggested that meibomian gland dropout visible within the upper and lower eyelids is a useful means of assessing meibomian gland dysfunction in dry eye. For the first time, it is possible to measure the tear film break-up time under infrared illumination, avoiding reflex tearing and using an objective computer-based analysis. As with other non-invasive assessments of tear film stability, the break-up time provides longer values than clinical assessment with fluorescein and may provide a more natural representation (Lan et al., 2014).

OCT Anterior Segment

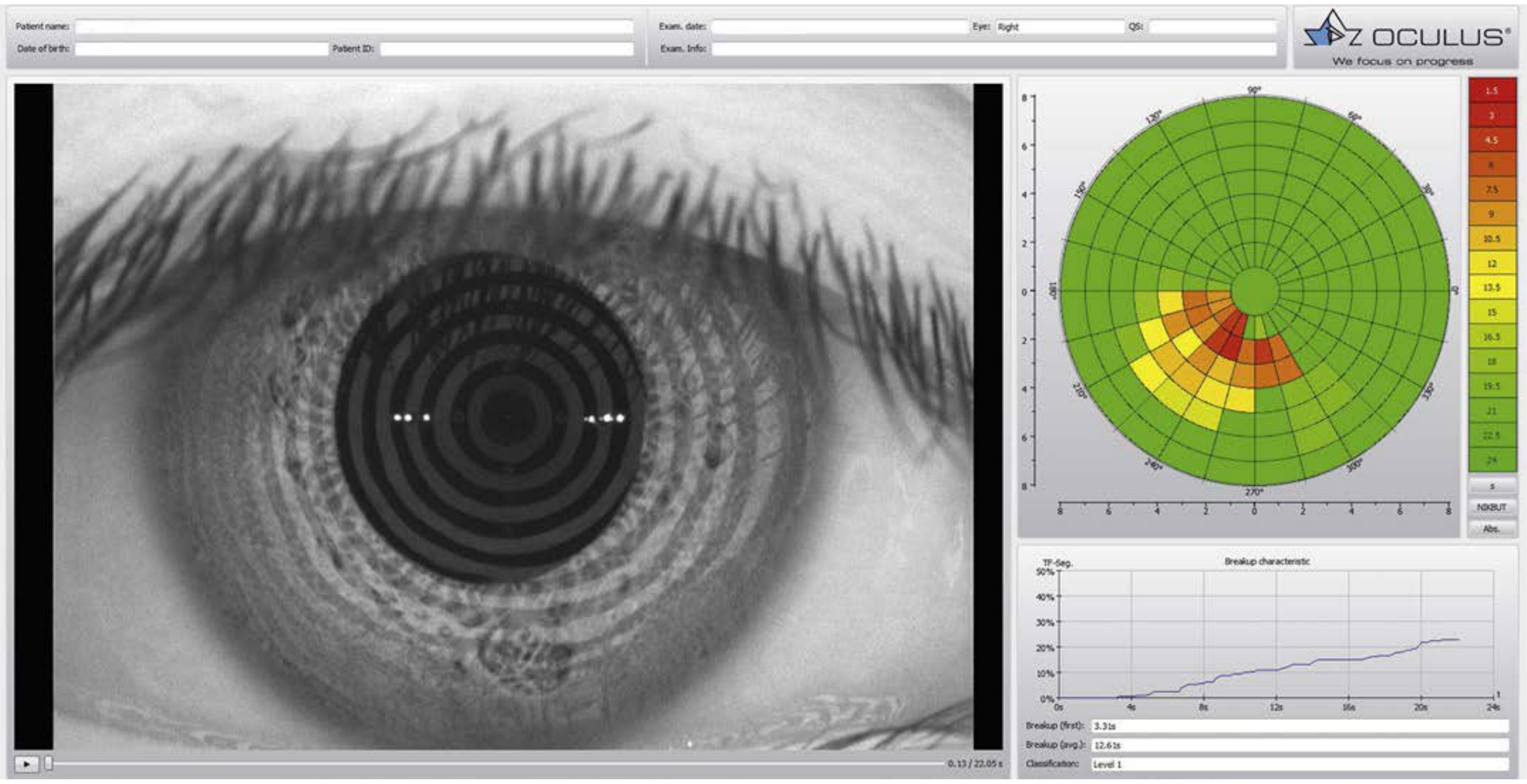
The newest imaging technology for contact lens practice is optical coherence tomography (OCT), which enables quantitative cross-sectional imaging of the anterior eye using infrared, low-coherence light. OCT is a significant advance in imaging because of the benefit of corneal tomography at very high speed (a fraction of a second), with great accuracy and the patient comfort associated with infrared light.

Dedicated anterior OCT instruments use a 1310 nm infrared diode for imaging. The long-wavelength light is able to penetrate both cornea and sclera, enabling imaging of not just the cornea but also structures inside the anterior angles and beneath the scleral surface, such as filtering blebs (Bruce, 2012).

Zeiss Visante (www.zeiss.com) was the original OCT instrument and, although that is now discontinued, the Tomey Casia SS-1000 (www.tomey.com) is a newer higher-speed alternative. Both instruments can image a volume up to 16 × 16 × 6 mm depth, and can present pachymetry analysis of a 10 mm diameter, with the Casia also giving corneal curvature and elevation analysis. Image examples are shown in Figs. 41.10 and 41.11. Posterior OCT instruments can potentially provide many of the pachymetry and corneal-imaging features of the dedicated anterior OCT.

Scanning Slit-beam Imaging

Scanning slit-beam instruments use visible light wavelengths to measure corneal tomography. By measuring both anterior and posterior corneal surfaces, a three-dimensional tomogram of the cornea is constructed and typically displayed


Patient name:
Date of birth:
Patient ID:
Exam. date:
Exam. Info:
QS:
OCULUS
We focus on progress
90°
120°
60°
150°
30°
180°
0°
210°
330°
240°
300°
270°
1.5
3
4.5
6
7.5
9
10.5
12
13.5
15
16.5
18
19.5
21
22.5
24
s
NIKBUT
Abs.
TF-Seg.
Breakup characteristic
50%
40%
30%
20%
10%
0%
0s
4s
8s
12s
16s
20s
24s
0.13 / 22.05 s

Eye: Right

Breakup (first): 3.31s

Breakup (avg.): 12.61s

Classification: Level 1

Fig. 41.8 Automatic detection of tear film break-up using the OCULUS Keratograph 5. (Courtesy of Oculus.)

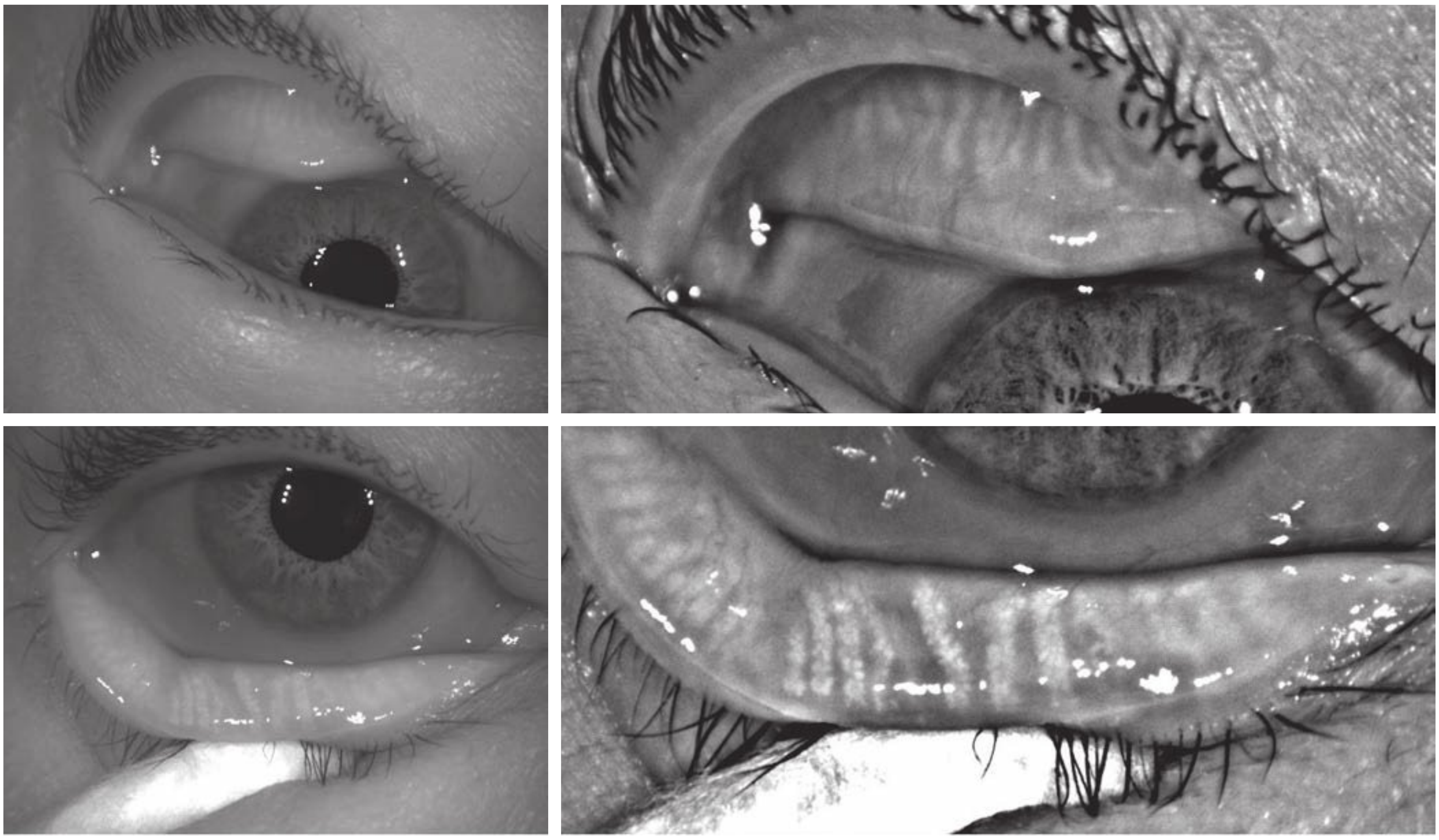


Fig. 41.9 Infrared imaging of the everted eyelids showing normal meibomian glands (left), with contrast enhanced images on the right.

as a quad-map (see Chapter 37). These instruments include the Pentacam, which uses a rotating Scheimpflug camera (www.oculususa.com) and the Orbscan II, which uses a scanning slit beam for corneal and anterior-chamber assessment (www.zyoptix.com). Scanning slit-beam instruments are mainly targeted at measurement, although the corneal slit images may be displayed.

Confocal Microscopy

Confocal microscopy is a specialized contact microscopy technique for corneal imaging. It gives magnification up to 400× with a small field of view. The technique shows the detail of individual cells in each layer of the cornea, allowing in vivo assessment of the effects of contact lenses, corneal infections,

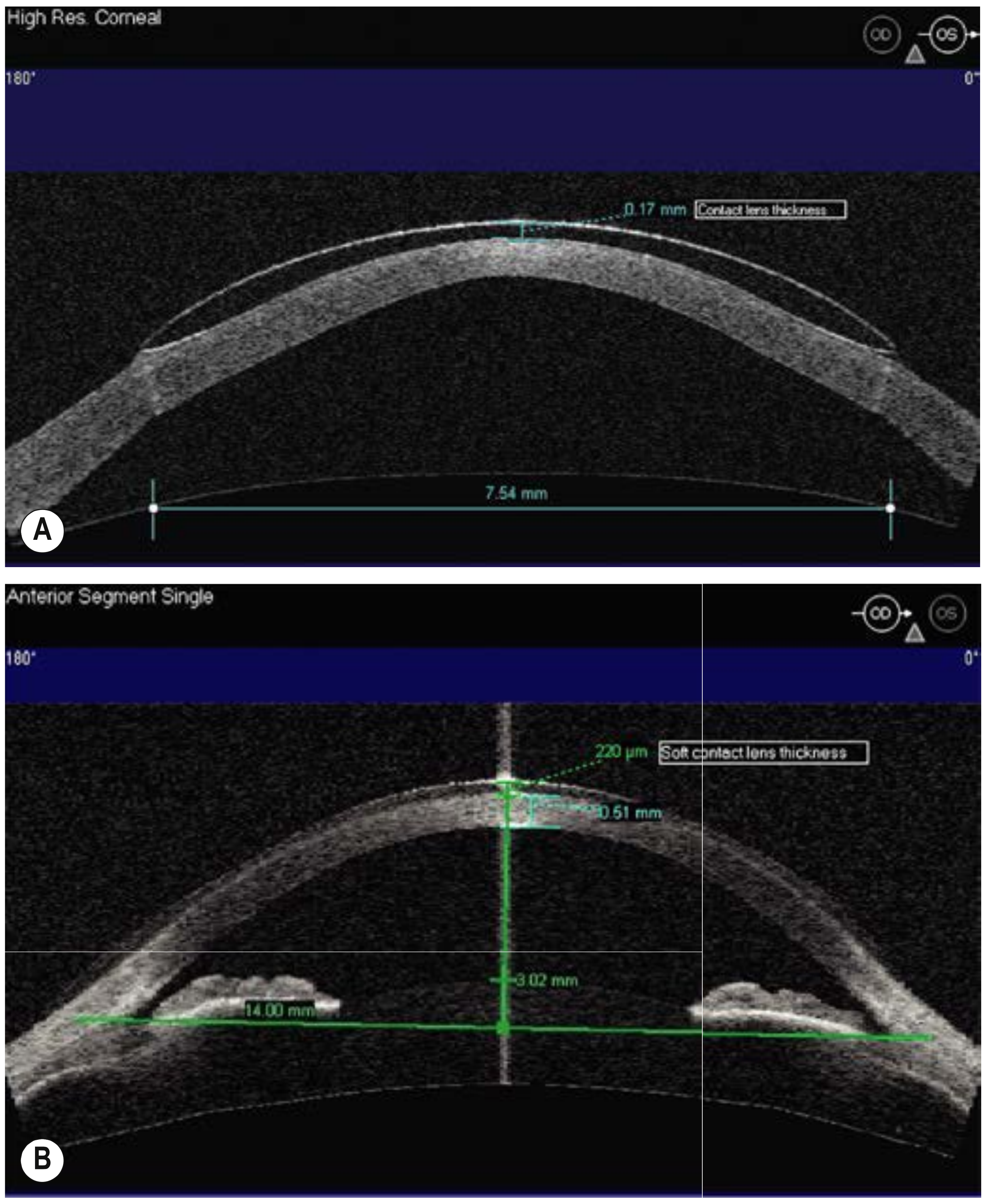
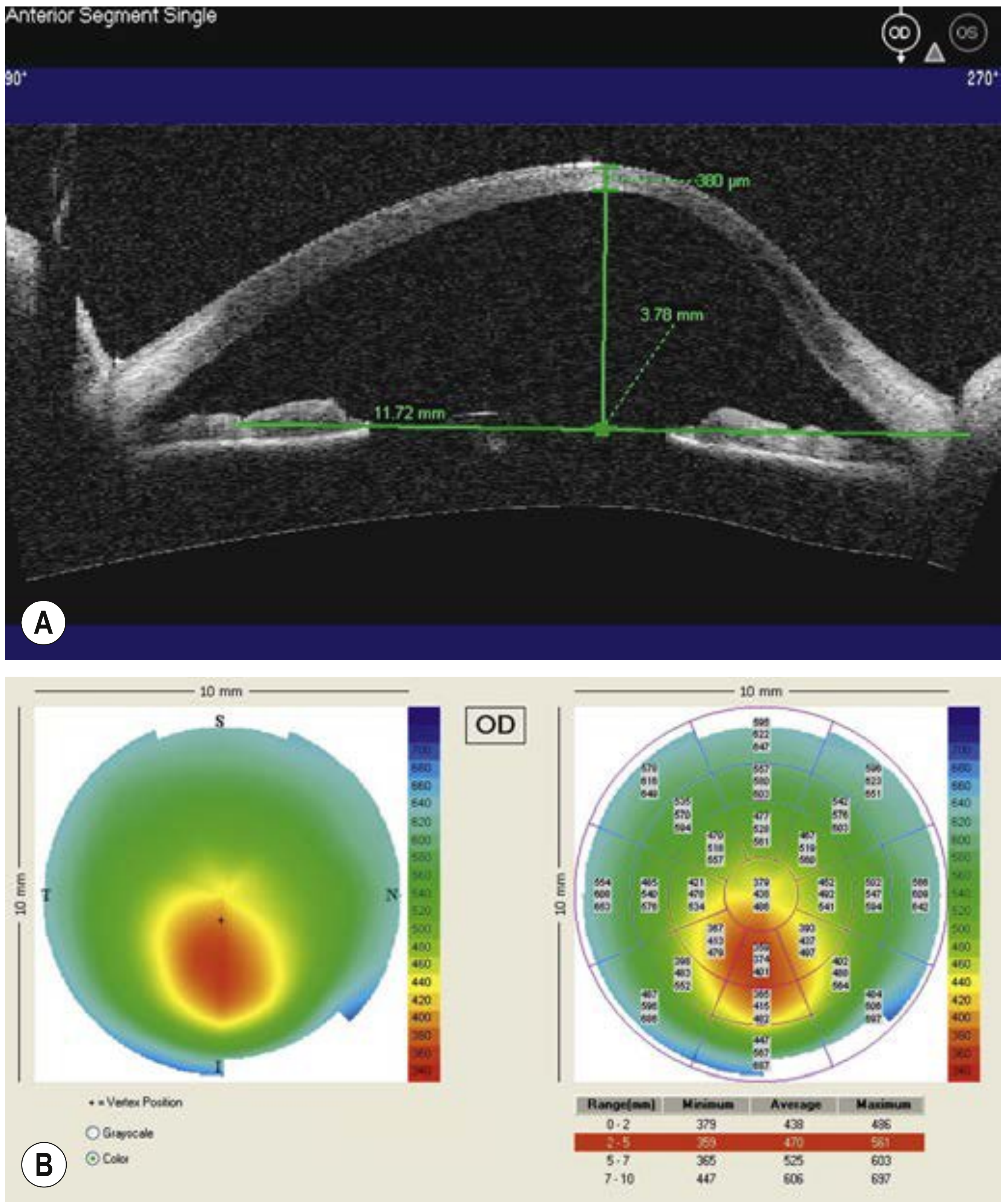

High Res. Corneal
OD
OS
180°
0°
0.17 mm
Contact lens thickness
7.54 mm
A
Anterior Segment Single
OD
OS
180°
0°
220 µm
Soft contact lens thickness
0.51 mm
3.02 mm
14.00 mm
B

Fig. 41.10 Optical coherence tomography (OCT) images of contact lenses. (A) Horizontal line scan (10 × 3 mm) of a rigid contact lens in moderate keratoconus. The central corneal thickness is 0.38 mm. (B) Horizontal line scan (16 × 6 mm) of a disposable soft contact lens for moderate hyperopia.


Anterior Segment Single
OD
OS
90°
270°
380 µm
3.78 mm
11.72 mm
A
10 mm
S
T
N
I
10 mm
OD
10 mm
10 mm
+ = Vertex Position
○ Grayscale
◉ Color
B

Range(mm)	Minimum	Average	Maximum
0 - 2	379	438	496
2 - 5	359	470	561
5 - 7	365	525	603
7 - 10	447	606	697

Fig. 41.11 Optical coherence tomography images in keratoconus. (A) Vertical line scan showing the cone profile, corneal thinning and increased anterior-chamber depth. (B) Map of corneal thickness in the same patient showing inferior corneal thinning.

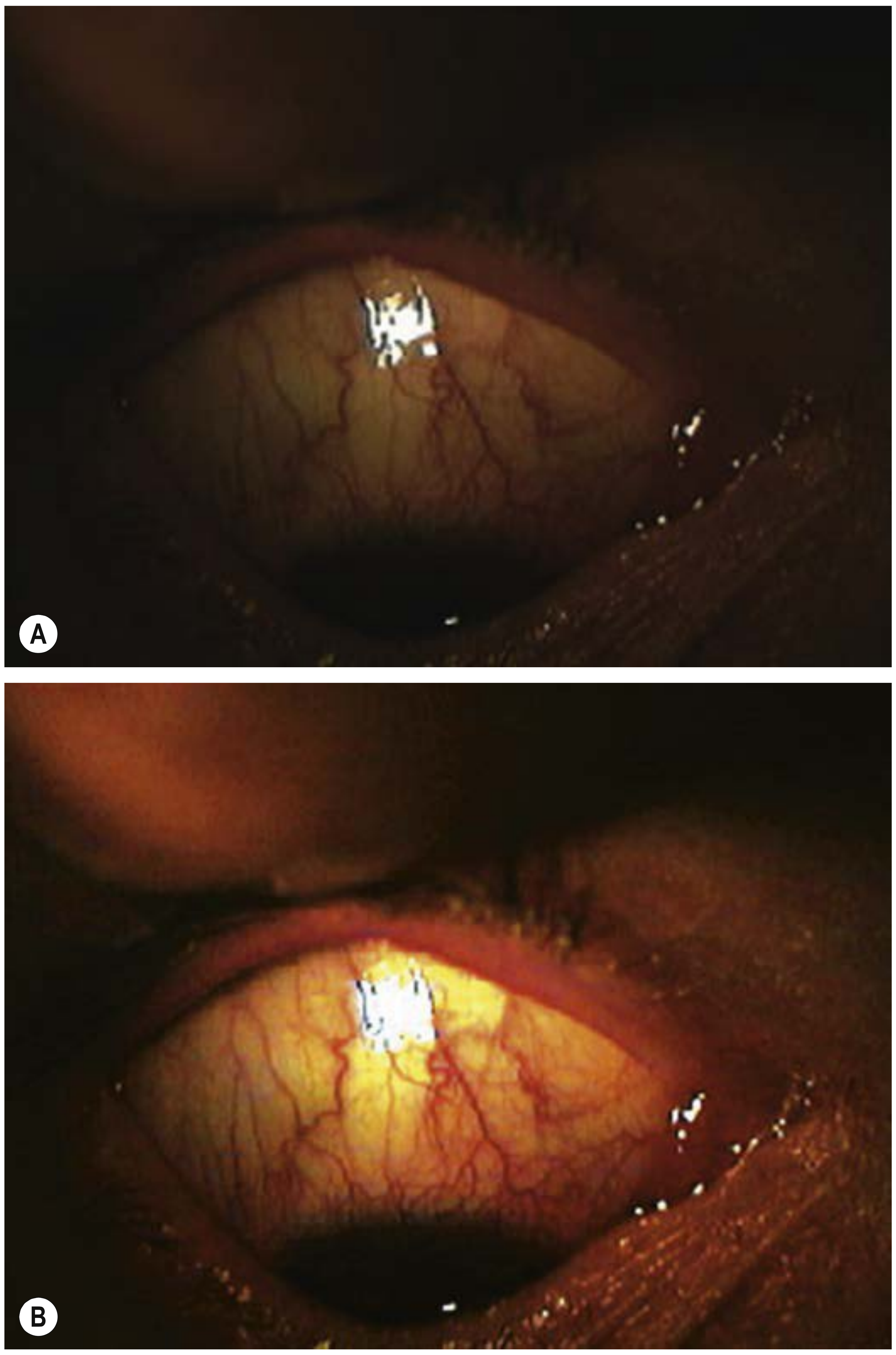


Fig. 41.12 Image enhancement. (A) The original dull image. (B) The same image after brightness and contrast enhancement.

inflammations and dystrophies (Efron and Hollingsworth, 2008; Pritchard et al., 2014). Available instruments include the Nidek Confoscan4 (www.nidek.com) and the Heidelberg Laser Scanning Confocal Microscope (www.heidelbergengineering.com).

Image Editing

Digital images have the advantage of image manipulation. There are many image-editing programs available on the market today. Basic image-editing capabilities are offered as a software feature in some commercial slit-lamp packages. Key editing applications with respect to contact lens imaging include the following:

- Brightness and contrast correction – images that are underexposed can be corrected easily with image editing (Fig. 41.12). The lightest pixel and darkest pixel in the picture specify each end of the spectrum. The remaining pixels are rescaled to fill out the rest of the spectrum (Hom and Bruce, 1998).
- Fluorescein pattern analysis – fluorescein pattern images can be analysed by colour (Costa and Franco, 1998). Objective methods can be used to determine the fit of a lens (flat, steep, aligned). The fluorescein pattern is analysed by RGB colour channels. The histograms of the blue and green channels can be used to differentiate between a flat, steep and aligned (on-K) fit (Hom and Bruce, 1998).

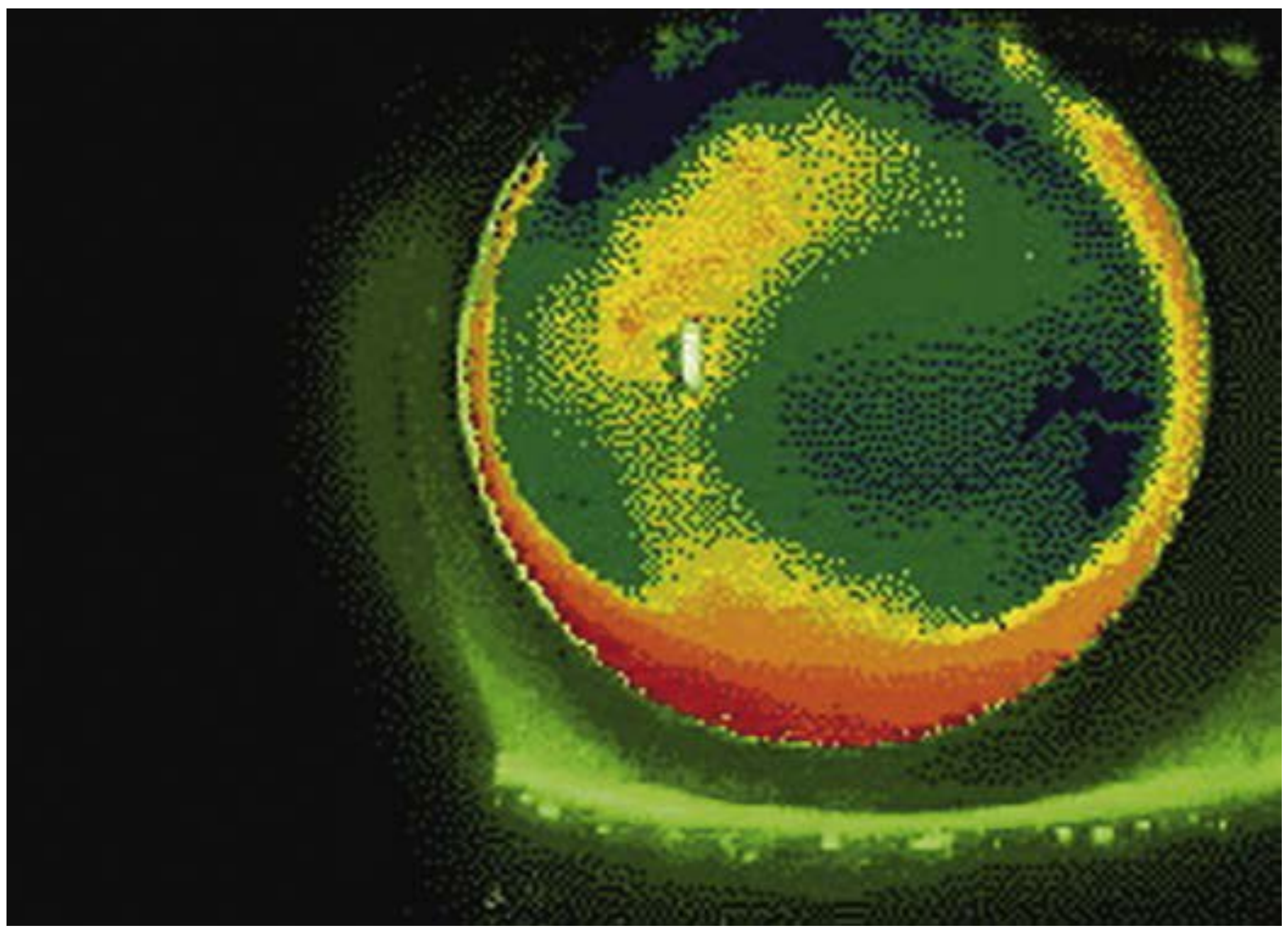


Fig. 41.13 Tear layer thickness pattern (see text).

- Tear layer thickness analysis – tear layer thickness under the lens can be determined by the intensity of the fluorescence. The thinner tear layers are dark. Thicker tear layers are brighter. Reducing the colour depth of a fluorescein pattern separates the colour differences between the thick and thin tear layers (Fig. 41.13). The different thickness areas are made even more distinct by applying new colours. The corneal topography underneath a rigid lens can be interpolated with this technique (Hom and Bruce, 1998).

Conclusion

Digital photography is a hugely advantageous technique for contact lens practice. Both commercial and smartphone imaging systems have become simpler and less expensive. This chapter has demonstrated the great potential and versatility of digital image capture systems for enhancing clinical care by improved recording and sharing of clinical information relating to contact lens practice. Digital imaging enhances patient communication and retention and supports practice growth.

Access the complete references list online at http://www.expertconsult.com.

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42

Compliance

NATHAN EFRON

Introduction

> Patients are often lying when they say they have regularly taken the prescribed medicine.
>
> **Hippocrates, 400 bc**

The issue that Hippocrates was highlighting was that of compliance – an important field of medicine that has been the subject of medical research since the beginning of the 20th century. In the contact lens field, studies of compliance commenced only in the mid 1980s, with the first peer-reviewed journal article on this topic being published in 1986 by Collins and Carney.

Although patients sometimes unwittingly, carelessly or even recklessly contribute to their own misfortune (Fig. 42.1), the model offered by Hippocrates is perhaps a little too simplistic. Sackett and Hayes (1976) defined compliance as 'the extent to which a patient's behaviour coincides with the clinical prescription'. This is a more instructive definition in that it highlights the critical importance of the practitioner–patient relationship in avoiding adverse events. This chapter will review the field of compliance as it relates to contact lens wear and will conclude with the presentation of a contact-lens-specific compliance model.

Consequences of Non-compliance

Although full compliance with practitioner instructions does not guarantee trouble-free lens wear (Najjar et al., 2004), it is worth considering the possible consequences of non-compliance because the conclusions from such an analysis provide the rationale for studying this topic. In general, non-compliance will result in the following adverse effects: reduction of treatment efficacy, secondary problems, incorrect prescribing, wasting of practitioner chair time, and wasting of patient time. Clearly, health-care delivery will be enhanced if adverse consequences of non-compliance can be minimized or eliminated.

Extent and Pattern of Non-compliance

It is not always possible to characterize a person simply as compliant or non-compliant, because there will be variations in the pattern of non-compliance over time, and changes in the extent of non-compliance at a given instance in time. Because of this, non-compliant behaviour in some people may continue undetected for some time. There is a greater likelihood of detecting consistent and / or total non-compliant behaviours at an aftercare visit.

Duration of the Prescription

In the general health-care field, the extent of non-compliance has been found to be related to the duration of the prescription. For short-term medication (e.g. a 9-day course of antibiotics) about 20–30% of patients will be non-compliant. Higher rates of non-compliance are found for long-term regimens: 30–40% of patients are non-compliant with preventive or prophylactic measures (e.g. using sun protection creams outdoors in patients susceptible to skin cancer) and more than 50% of patients do not adhere to advice relating to long-term therapy (e.g. ongoing medication for chronic hypertension) (DiMatteo and DiNicola, 1982; Claydon and Efron, 1994a).

The prescription of contact lenses and contact lens care systems is akin to a long-term preventive measure; it is therefore not surprising that in 2011 an international survey of 4021 lens wearers found that full compliance with all aspects of the lens care regimen was very rare for most lens users, although better (15% of wearers) for daily disposable lenses (Morgan et al., 2011). Claydon and Efron (1994b) had noted similar levels of contact lens non-compliance 17 years earlier, indicating that little has changed in this regard in the intervening period. Levels of non-compliance with respect to contact lens care are broadly consistent with estimates of patient non-compliance reported in general medicine (Claydon and Efron, 1994a).

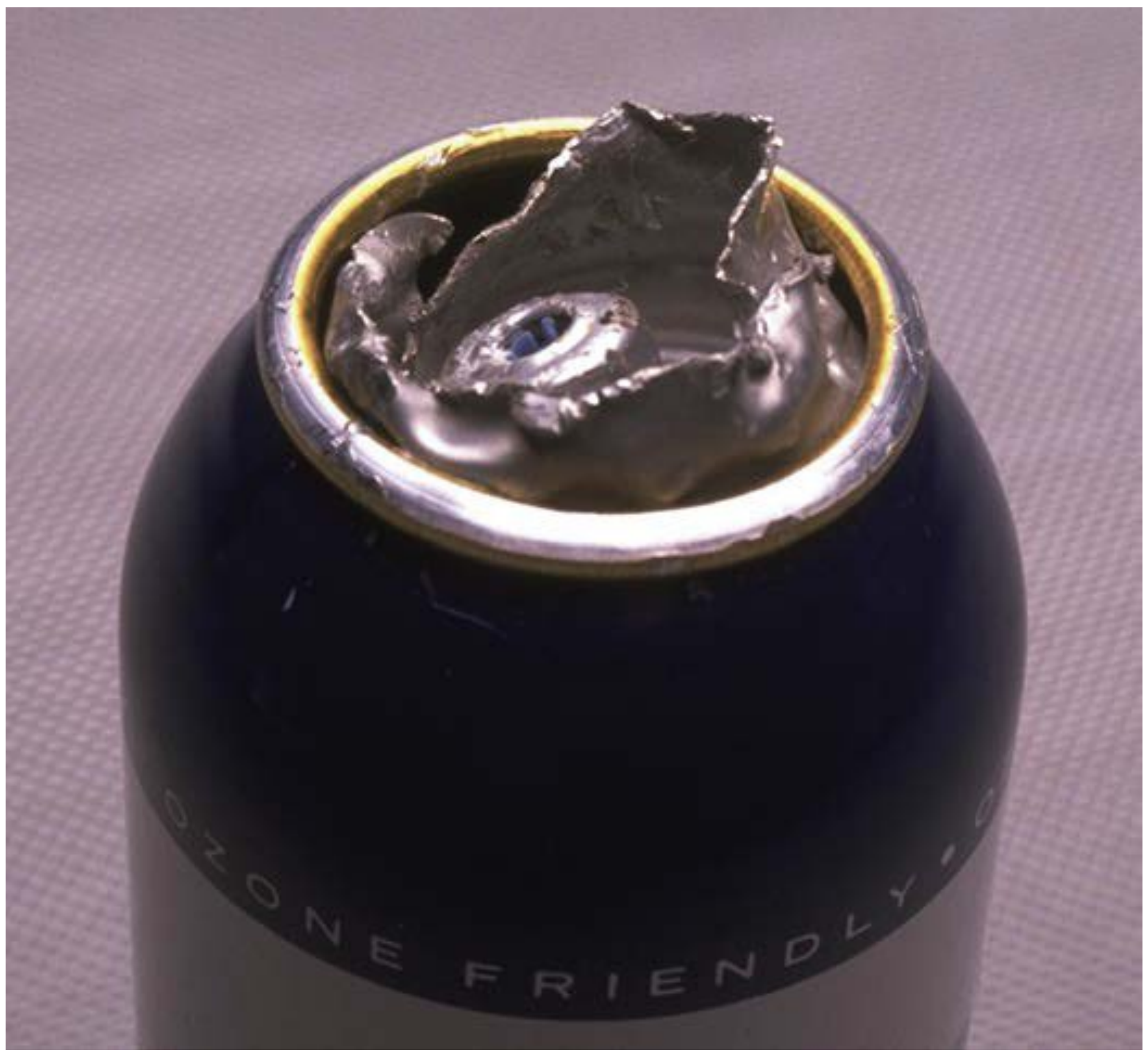

Fig. 42.1 Reckless attempt by a patient to obtain residual solution from a can of aerosol saline (because the nozzle had ceased to function) by sawing the top off. (Courtesy of Jane Veys.)

Erroneous Contact Lens Procedures

A number of epidemiological studies have identified risk factors that are associated with an increasing likelihood of microbial keratitis during contact lens wear (Morgan et al., 2011). Many of these are 'non-modifiable' and include age, gender and socio-economic status. Others are 'modifiable'; in turn, these can be subdivided into factors that are or are not related to 'compliance'.

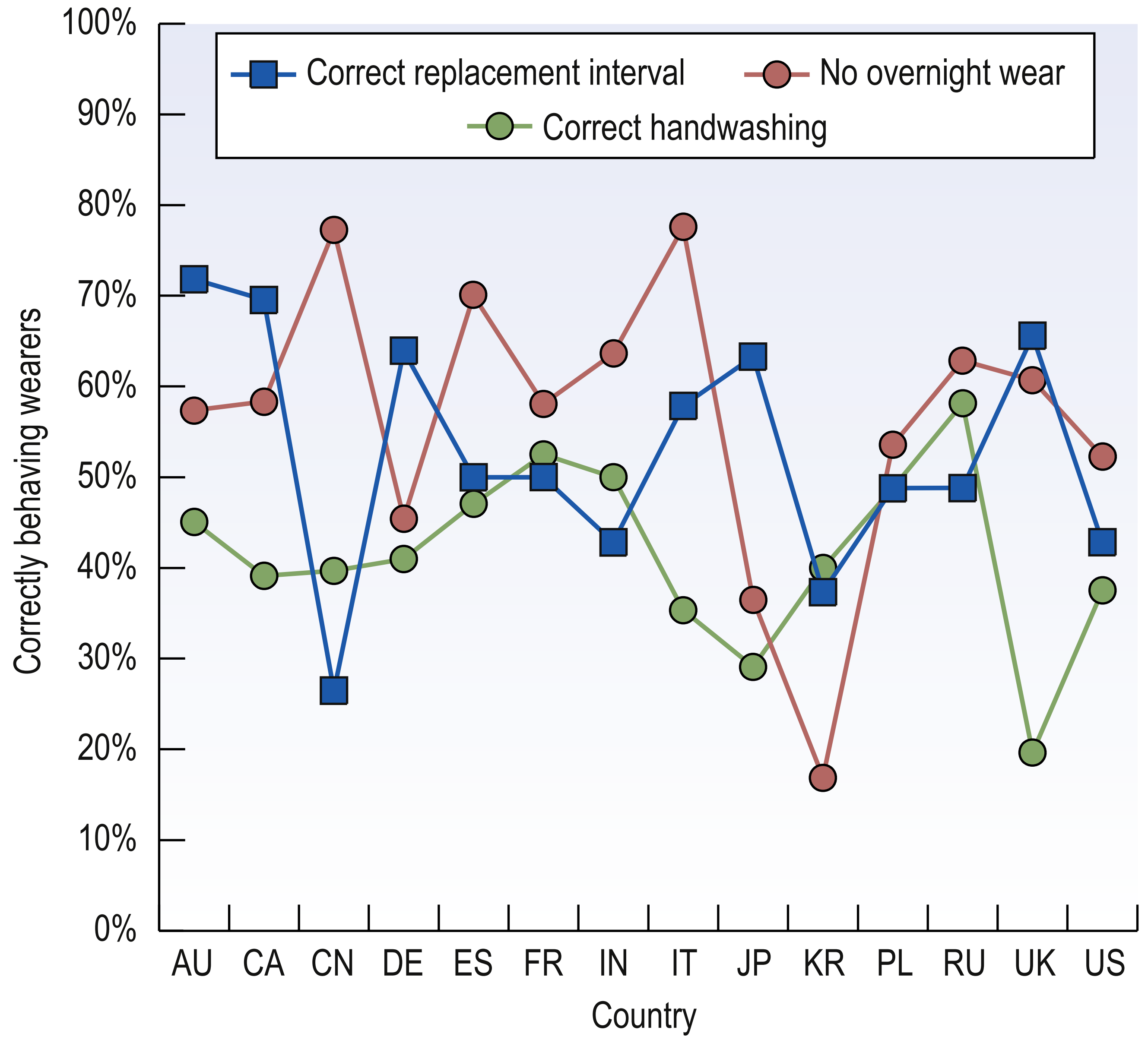

Fig. 42.2 Proportion of correctly behaving wearers for modifiable patient-compliance-related behaviours for daily disposable lenses. Country codes: AU= Australia; CA= Canada; CN= China; DE= Germany; ES= Spain; FR= France; IN= India; IT= Italy; JP= Japan; KR= South Korea; PL= Poland; RU= Russia, UK= United Kingdom, US= United States. (From Morgan, P. B., Efron, N., Toshida, H. & Nichols, J. J. (2011). An international analysis of contact lens compliance. Cont. Lens Anterior Eye, 34, 223–228.)

Morgan et al. (2011) identified eight modifiable, patient-compliance-related behaviours that put the patient at increased risk for microbial keratitis:

- inadequate handwashing
- non-prescribed overnight wear
- excessive duration of extended wear
- excessive lens replacement interval
- inadequate case cleaning
- failure to use correct disinfecting solution
- failure to rub and rinse lenses
- topping up solution.

Surveys conducted in 14 countries identified the proportion of correctly-behaving wearers for modifiable patient-compliance-related behaviours (MPCRBs) for daily disposable lenses (Fig. 42.2) and daily-wear reusable lenses (Fig. 42.3) (Morgan et al., 2011). Statistical analysis revealed that, overall, country was a significant independent factor in predicting the total number of non-compliant steps. The key difference here was the greater number of non-compliant MPCRBs reported by South Korean respondents, with a largest least mean square (LMS) value of 3.97 compared with the other countries, which ranged from 2.93 in France to 3.45 in Japan.

The number of non-compliant steps also differed across the lens types. Daily disposable lenses were associated with the least non-compliance, followed by reusable extended-wear soft lenses and the remaining lens groups (reusable daily-wear soft planned replacement lenses, non-planned replacement soft lenses and rigid lenses) performing similarly.

Gender was predictive of the number of non-compliant MPCRBs, with better compliance for women (3.12) than for men (3.28). Age was also demonstrated to be an important factor, with the number of non-compliant steps diminishing with the age of the respondent. The rate of improvement with age was about 0.15 non-compliant MPCRBs per decade of life.

Respondents using their lenses more frequently tended to be less compliant than did those using lenses on a part-time

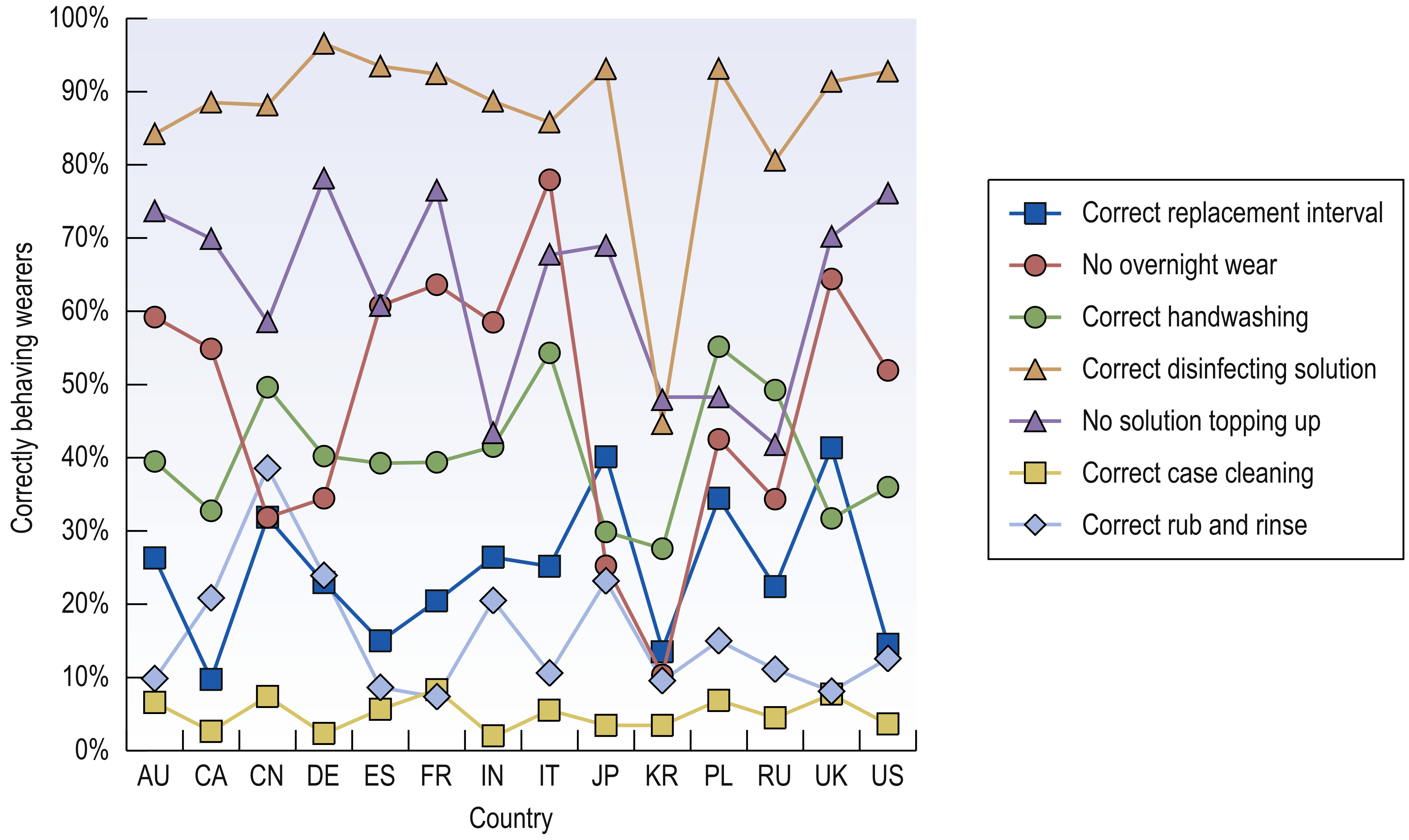

Fig. 42.3 Proportion of correctly-behaving wearers for modifiable patient compliance–related behaviours for daily wear reusable lenses. (Country codes as in Fig. 42.2.) (From Morgan, P. B., Efron, N., Toshida, H. & Nichols, J.J. (2011). An international analysis of contact lens compliance. Cont. Lens Anterior Eye, 34, 223–228.)

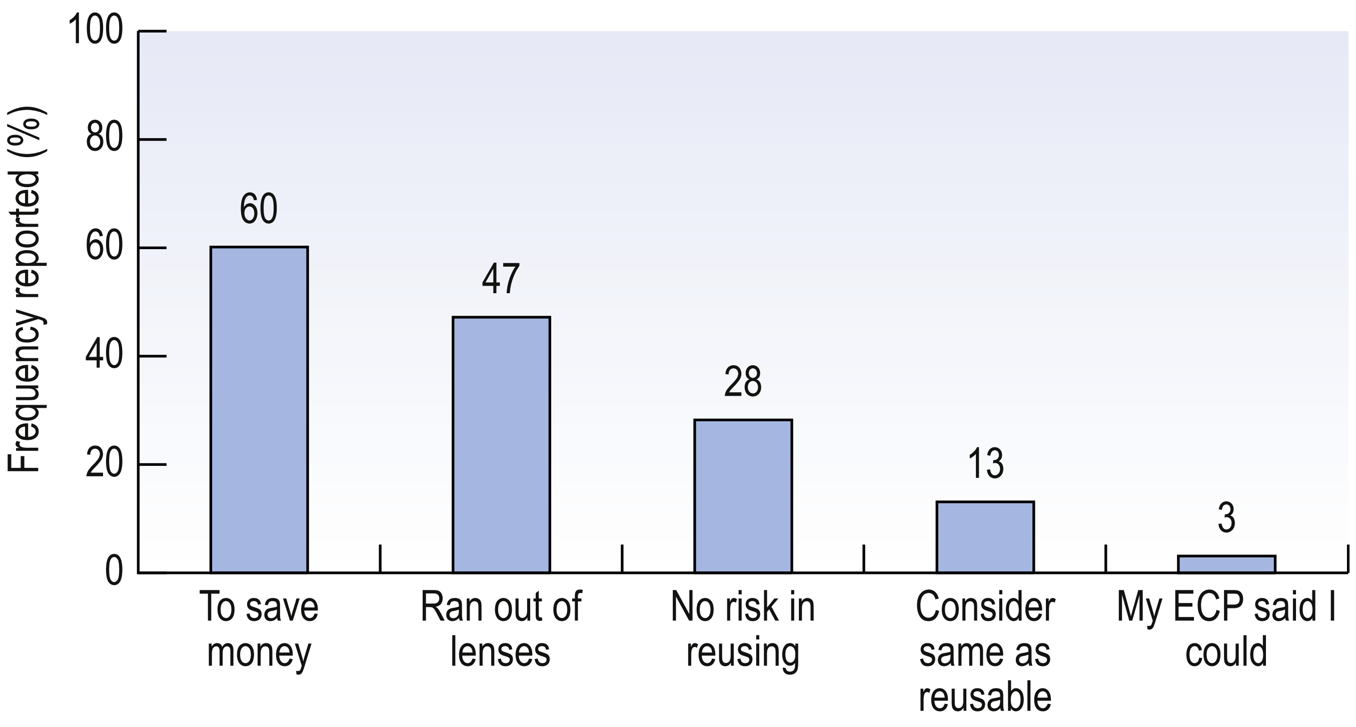

Fig. 42.4 Reasons for re-use of daily disposable contact lenses. (From Dumbleton, K. A., Richter, D., Woods, C. A. et al. (2013a). A multi-country assessment of compliance with daily disposable contact lens wear. Cont. Lens Anterior Eye, 36, 304–312.)

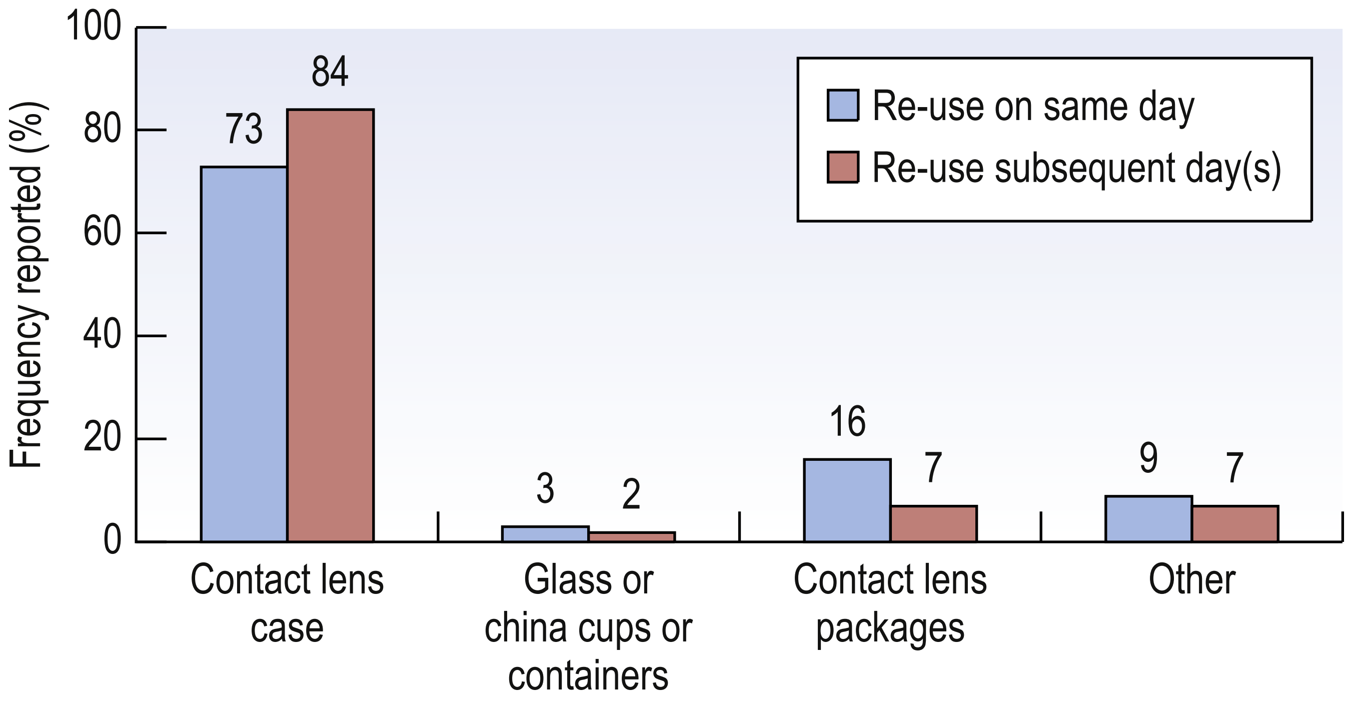

Fig. 42.5 Method of storing re-used daily disposable contact lenses. (From Dumbleton, K. A., Richter, D., Woods, C. A. et al. (2013a). A multi-country assessment of compliance with daily disposable contact lens wear. Cont. Lens Anterior Eye, 36, 304–312.)

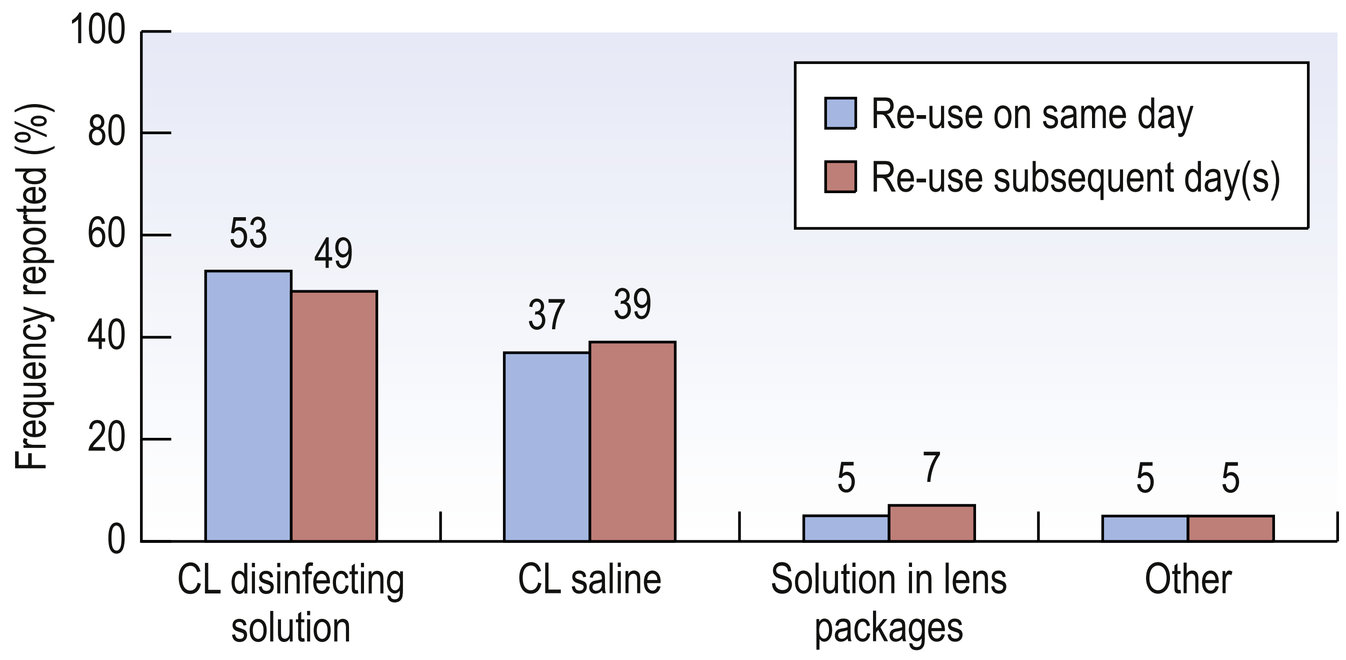

Fig. 42.6 Solution used to store reused daily disposable contact lenses. (From Dumbleton, K. A., Richter, D., Woods, C. A. et al. (2013a). A multi-country assessment of compliance with daily disposable contact lens wear. Cont. Lens Anterior Eye, 36, 304–312.)

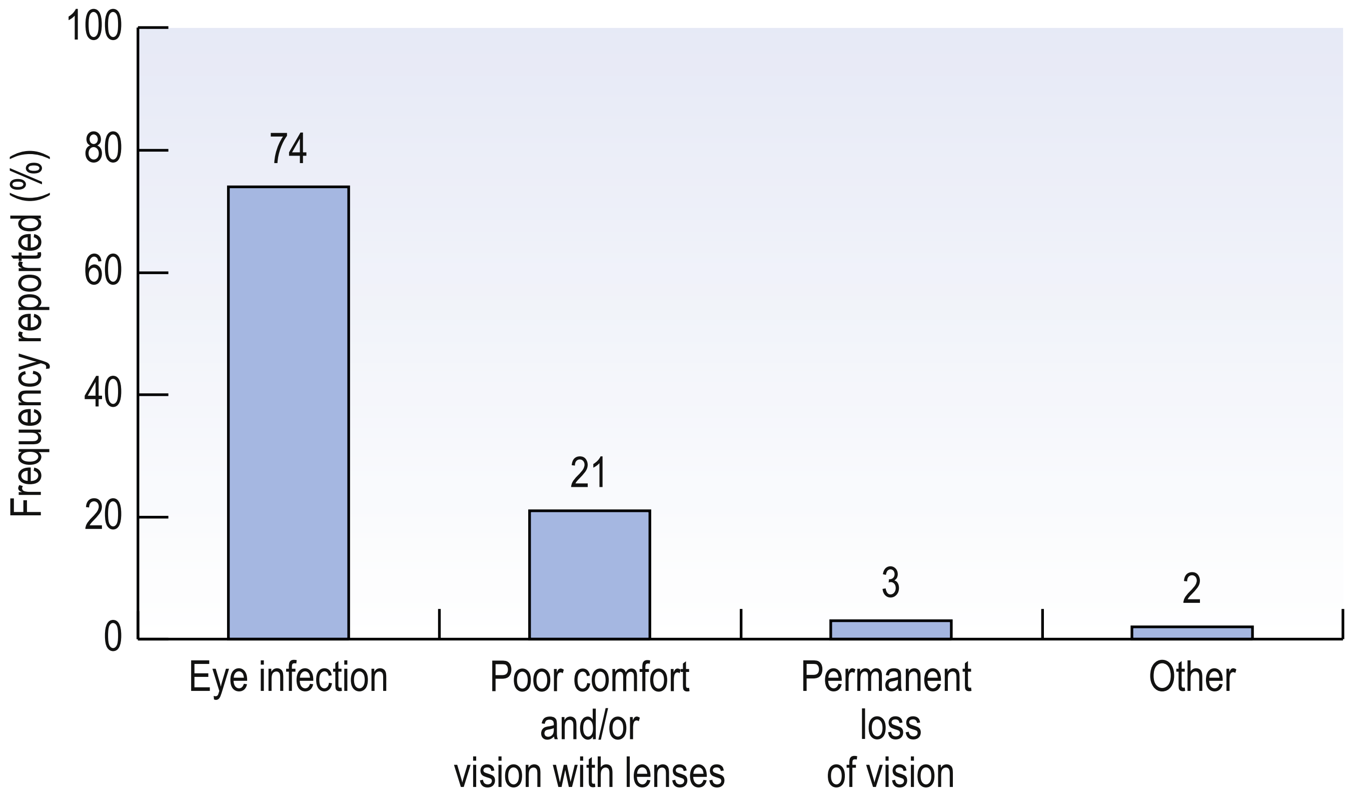

Fig. 42.7 Patient perceptions of the main risk of rewearing daily disposable contact lenses. (From Dumbleton, K. A., Richter, D., Woods, C. A. et al. (2013a). A multi-country assessment of compliance with daily disposable contact lens wear. Cont. Lens Anterior Eye, 36, 304–312.)

basis. Subjects using lenses on a full-time basis typically performed 3.47 non-compliant MPCRBs compared with 2.41 non-compliant steps for those using lenses for a single day per week. Respondents were more compliant if they had consulted with an eye-care practitioner more recently (Morgan et al., 2011).

Reasons for Non-compliance

Dumbleton et al. (2013a) surveyed 805 patients wearing daily disposable contact lenses in four countries – Australia, Norway, the United Kingdom and the United States – to determine the rate of non-compliant behavior and the reasons for this. Although daily disposable lenses are designed to be worn once only and discarded after each use, overall 9% of patients were non-compliant, with the specific rates of non-compliance in the four countries being: Australia 18%, USA 12%, UK 7% and Norway 4%.

The reasons patients gave for reuse of lenses is shown in Fig. 42.4. Among those who did reuse their daily disposable lenses, various methods were used to store lenses overnight (Fig. 42.5) and a number of different of solutions employed for this purpose (Fig. 42.6). Patient perceptions of the main risk involved in reusing daily disposable lenses are shown in Fig. 42.7 (Dumbleton et al., 2013a) Similar reasons for non-compliant behaviour in the United States have been reported for reusable lenses (Dumbleton et al., 2013b), with one key difference: the main reason cited for wearing reusable lenses longer than recommended was forgetfulness – either forgetting which day to replace lenses or forgetting to reorder lenses.

Compliance with the Incorrect Prescription

The vast majority of practitioners endeavour to dispense the correct and proper prescription; it would be unethical to do otherwise. However, in the past there have been well-documented contact-lens-related cases of practitioners dispensing the incorrect prescription based on misinformation or a misinterpretation (Efron et al., 1991; Matthews et al., 1992; Dumbleton et al., 2010). An example of this was the recommendation by 6% and 4% of practitioners in Canada and the USA, respectively, that patients reuse their daily disposable lenses (Dumbleton et al., 2010).

Whether inadvertent or deliberate, incorrect prescribing is a reality that must be considered in order to provide a comprehensive analysis of non-compliance. Fig. 42.8 is a flow diagram that reveals five possible outcomes based upon the assumption that an incorrect prescription (or incorrect advice) has been dispensed to the patient. A tick indicates the likelihood of a positive outcome, and a cross indicates the likelihood of a negative outcome.

If the patient is compliant with the incorrect prescription then a negative outcome, such as ocular irritation, is more likely. A patient may also be non-compliant with the incorrect prescription. Non-compliance can be deliberate or unintentional, and a patient can be deliberately non-compliant in a rational or irrational manner. Unintentional non-compliance can be due to forgetfulness or a misunderstanding of the instructions. It is unlikely

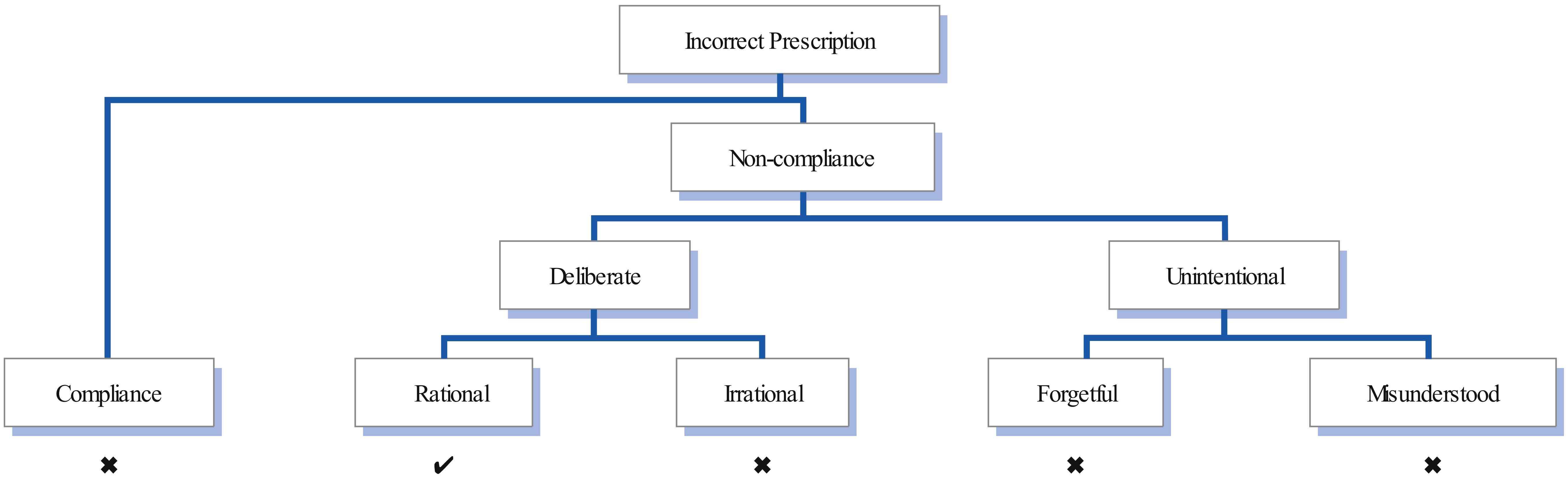

Fig. 42.8 Consequences of compliance with the incorrect prescription (a tick indicates the likelihood of a positive outcome and a cross indicates the likelihood of a negative outcome).

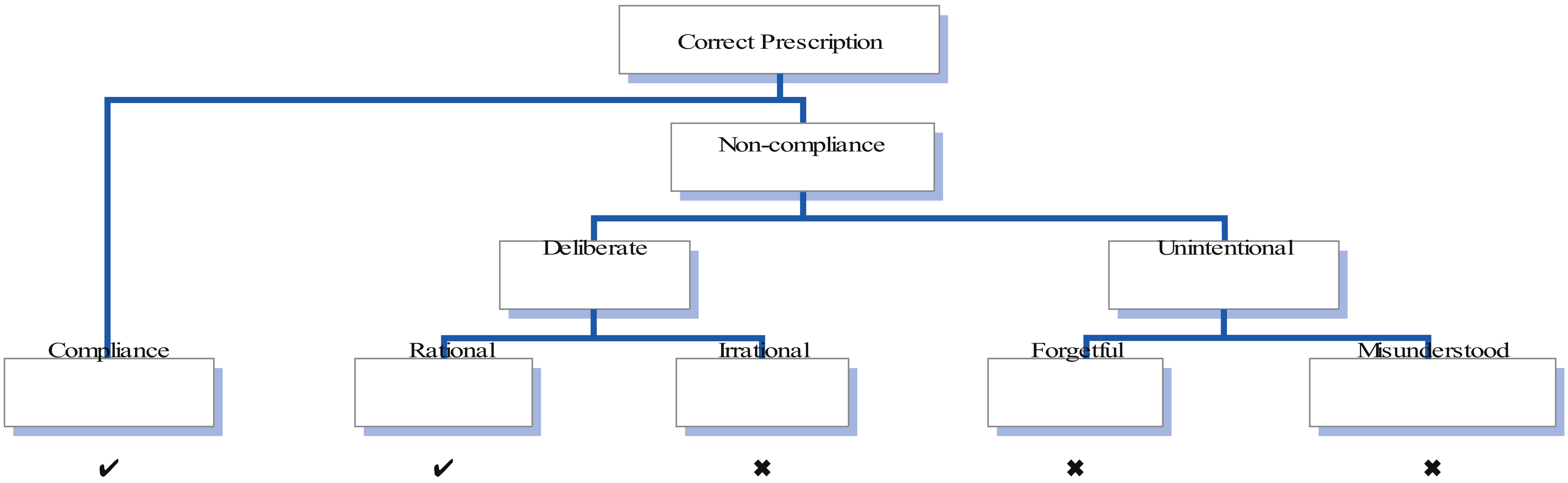

Fig. 42.9 Consequences of compliance with the correct prescription (a tick indicates the likelihood of a positive outcome and a cross indicates the likelihood of a negative outcome).

that unintentional non-compliance will result in correct procedures being readopted because of the plethora of random and most likely erroneous procedures that are theoretically available.

Compliance with the Correct Prescription

A patient being non-compliant with the correct prescription probably constitutes the classical view of non-compliance taken by practitioners. Fig. 42.9 is a flow diagram that reveals five possible outcomes based upon the assumption that a correct prescription (or correct advice) has been issued. If the patient is compliant with the correct prescription, a positive outcome is more likely. Conversely, a negative outcome is likely if a patient is non-compliant with the correct prescription.

Investigation of Strategies for Compliance Enhancement

Vincent (1971) conducted a study on a large cohort of glaucoma patients who were specifically told that if they did not comply with the instruction to instill three drops of topical medication into their eyes daily they could go blind. The outcome of the study was that 50% of patients did not comply often enough, and that there was no improvement in compliance in those who lost sight in one eye.

In the light of such results, one may wonder whether anything can be done to improve compliance among contact lens wearers, especially in view of the fact that the consequences of non-compliance, such as the development of a corneal ulcer, carry a very low absolute risk. A more enlightened approach might be to assume that there will always be a certain level of non-compliance, and that contact lenses and lens care systems should be designed to have a sufficient level of redundancy, or safety margin, to account for this.

Notwithstanding the above reservations, the search for viable compliance enhancement strategies needs to continue in view of the known adverse consequences of non-compliance.

Because contact lens wearers typically overestimate their level of compliance (Donshik et al., 2007), strategies in addition to the use of questionnaires must be adopted to derive an accurate picture of the level of adherence to instruction. Such strategies include, but are not limited to: observation and scoring of patient actions and procedures in a clinical situation, direct determination of the number of lenses used or care solution volumes remaining over fixed time frames, and anonymous surveys of contact lens behaviours and beliefs.

IMPROVING INITIAL PATIENT EDUCATION

Claydon et al. (1997) conducted a 12-month study on 80 patients who were randomly divided into two groups. One group was given standard verbal instructions, and the other group was subjected to a compliance enhancement strategy. Handwashing was the only procedure that improved to an extent that was statistically verifiable. In contrast, the intensity of initial education had no bearing on the integrity of the anterior ocular structures. Thus, the compliance enhancement strategy failed, indicating that a level of instruction in excess of that typically being offered at the present time is likely to be redundant in terms of enhancing compliance.

There may be other benefits of a thorough initial education, such as: (1) raising awareness of lens types and lens care products, (2) reinforcing brand loyalty (if this is of interest), and (3) enhancing the patient–practitioner relationship. Although an enhanced initial instruction will not improve compliance, the benefits of reinstruction are clear. Compliance can be enhanced by constantly reminding patients of correct procedures at aftercare visits (Capellani and Boyce, 1999). Radford et al. (1993) demonstrated that such an approach improved the rate of compliance in one study group from 44% to 90%.

PERIODIC SELF-REVIEW

Yung et al. (2007) administered a regular self-review exercise on proper lens handling to a group of 60 lens wearers once every 3 months for 12 months. The levels of compliance and contamination of contact lenses and lens care accessories between the test group and control group (the latter was not administered a regular self-review) were compared at the end of the 12-month period so as to evaluate the effect of the intervention. All showed some degree of non-compliance in the care of their contact lenses and lens accessories. Most (about 60%) were non-compliant with at least six of a total of 15 lens care procedures. The most common non-compliant behaviour among contact lens wearers was associated with the care of the lens case. By the end of the study period, the compliance enhancement strategy did not appear to have had any significant effect on the behaviour of the subjects, except for improvement in the care of lens cases.

REDUCING COST

Sheard et al. (1995) conducted a 4-month study on 59 patients who were randomly divided into two groups. The 'full-pay' group paid the full retail price of lens care products, whereas the 'nominal-pay' group paid a nominal fee for their lens care products. Sheard et al. (1995) found that reducing cost did not affect compliance as measured by solution usage or procedure demonstration. Had this experiment been conducted the other way around – by determining the level of compliance as the cost of care products is increased – it would have been possible to determine a threshold cost above which patients become dangerously non-compliant. Of course, such an experimental approach is not possible.

The ability of patients to pay for health care was studied by de Andrade Sobrinho and Carvalho (2003), and related to the extent of compliance with contact lens care and wear regimens. The authors found no correlation, and concluded that socioeconomic factors do not seem to have an impact on compliance with contact lens care routines.

Predicting Non-compliance

Many of the problems relating to non-compliant patient behaviour could be overcome if it were possible to predict which patients were less likely to be compliant. Unfortunately, most attempts at identifying such predictors have been unsuccessful. For example, Davidson and Akingbehin (1980) failed to find an association in general ophthalmological practice between non-compliance and the following personal and sociological characteristics: age, sex, race, occupation or socioeconomic status.

Interestingly, Chun and Weissman (1987) were able to identify one potentially useful predictor of non-compliance relating to contact lens wear – patient age. They found that patients under the age of 30 years and over the age of 50 years were more likely to display non-compliant behaviour. Morgan et al. (2011) also observed higher rates of non-compliance in younger lens wearers.

Claydon (1995) investigated the possibility that measurement of certain personality traits can be used to predict the likelihood or otherwise of compliance. She conducted a study in which the level of compliance with a simple contact lens regimen was measured on 48 contact lens wearers using demonstration and questionnaire techniques. The subjects also completed a psychological test known as the 16PF inventory (Cattell et al., 1988) and the data were examined for possible associations. No overall correlations linking personality with compliance were revealed, although some interesting individual correlations were found. The personality trait 'adherence' was found to be associated with the thoroughness of case cleaning and surfactant cleaning. The personality trait 'extroversion' was found to be associated with the thoroughness of disinfecting and handwashing. Further work in this area may eventually lead to the formulation of a useful predictive test that can be applied clinically, such as a short questionnaire that could be quickly analysed and yield a score that could predict the likelihood of compliance.

Cardona and Llovet (2004) used an oral and a written comprehension test to establish the comprehension skills typology of contact lens wearers, thus allowing for the appropriate type of instructions (oral or written) to be given to each patient in accordance with their particular abilities. These authors suggested that this approach could enhance compliance among contact lens wearers.

The notion that contact lens wearers who are under strict life-preserving medical regimens and understand the value of general medical compliance will be more compliant with their contact lens wear behaviours was tested by O'Donnell and Efron (2004). Specifically, they hypothesized that diabetic contact lens wearers may represent a special group displaying higher levels of compliance with their lens care regimens as a result of learned behaviour relating to maintenance of their diabetic condition. Although the combined population of 29 diabetic and 29 non-diabetic contact lens wearers was generally found to be compliant, there were examples of non-compliance in both groups. Neither the duration of diabetes nor the degree of metabolic control appeared to related to compliance. The results suggest that associated health compliance behaviours are poor predictors of compliance with instructions relating to contact lens wear and care.

A Compliance Enhancement Model

Notwithstanding the difficulties discussed above in devising strategies to enhance or predict compliance, it is possible to construct a specific model for compliance enhancement in a contact lens setting based upon a wealth of evidence published in the contact lens field, and drawing upon the extensive literature defining the determinants of compliance in general health care. This model comprises four components: (1) the clinic and the practitioner, (2) the patient, (3) the advice that is given, and (4) the contact lens industry. In essence, the model amounts to a set of general principles and guidelines for enhancing compliance. Each component of the model will be considered in turn.

THE CLINIC AND PRACTITIONER

The clinic must have the following qualities:

- Staff should be informed and aware of key issues.
- Advice given should be consistent over time and between personnel.
- Appointment times should be individualized (as opposed to block booking).
- Waiting times should be minimal.
- There should be continuity of care wherever possible.
- The clinical environment should be warm and friendly.

Important qualities of the practitioner are as follows:

- Project a devotion to eye care (virtually all eye-care practitioners are devoted to eye care, but this is not always outwardly projected).
- Listen effectively to what the patient has to say.
- Use minimum jargon.
- Emphasize key points, especially following delivery of a long and perhaps complex set of instructions.
- Set specific and realistic goals for patients to aim at.
- Adopt strategies to motivate patients.

Strategies for optimizing the effectiveness of the aftercare visit include:

- Sending appointment reminders.
- Advising patients of the importance of regular check-ups.
- Providing feedback and reward to patients.
- Repeating key information.
- Stimulating any interest the patient has in the eye and vision.
- Providing in-practice information via leaflets, posters and videos.

THE PATIENT

A valuable approach to learning patient attitudes is to explore their health beliefs (Sokol et al., 1990) using a compliance decision tree. Fig. 42.10 is a diagram of such a decision tree. The answers to the sequence of questions posed in the decision tree will indicate whether or not the patient is likely to be compliant with instructions relating to contact lens wear. For example, Fan et al. (1995, 2002) found that, among contact lens wearers, those who had previously suffered from lens-related microbial keratitis believed more strongly than controls who had never suffered from keratitis in the perceived benefit of checking initially with the optometrist for the correct method of wearing reusable lenses.

If it is determined that the health beliefs of the patient are likely to lead to non-compliance, steps should be taken to modify the specific beliefs that are erroneous. This can be achieved via a variety of strategies, such as talking persuasively, supplying pertinent information or utilizing a health-care contract that emphasizes the responsibilities of the patient for achieving safe and comfortable ocular health during lens wear.

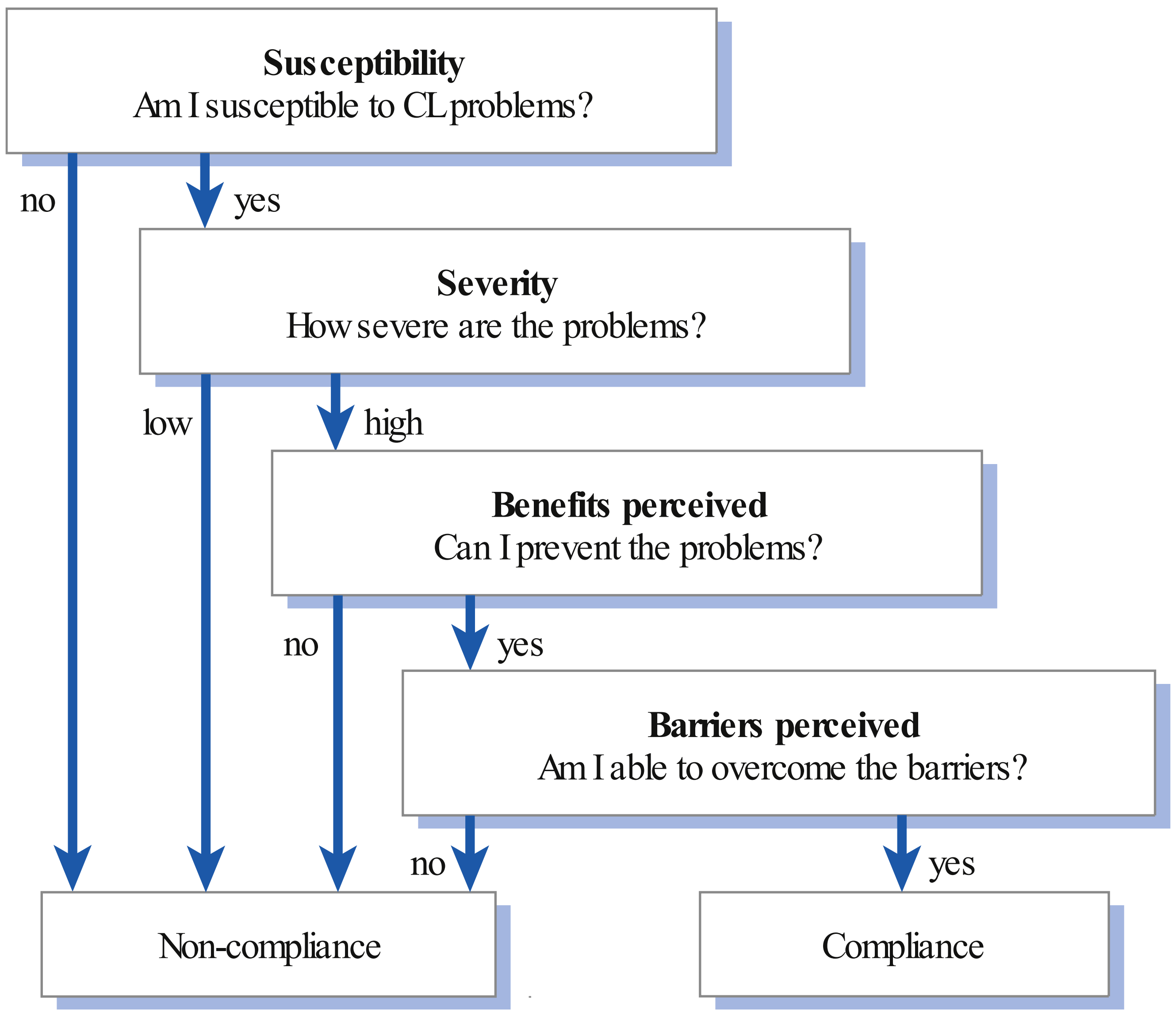
Susceptibility
Am I susceptible to CL problems?
no
yes
Severity
How severe are the problems?
low
high
Benefits perceived
Can I prevent the problems?
no
yes
Barriers perceived
Am I able to overcome the barriers?
no
yes
Non-compliance
Compliance

Fig. 42.10 The decision tree that can be used to explore how the health beliefs of a contact lens (CL) patient may influence his/her level of compliance.

THE ADVICE

Care systems should be simple and easy to understand, tailored for the individual, ritualized and not too expensive. Advice given to patients should be verbal and written. Printed material should be readable and well illustrated. Clearly illustrated sequential steps with minimum wording will aid understanding and interpretation. Written material should also contain warnings; obviously, a balance must be found whereby patients are alerted to possible dangers but are not frightened away from wearing lenses.

THE CONTACT LENS INDUSTRY

An important role is played by the contact lens industry in compliance enhancement – a role that falls into three broad categories:

1. Pricing policy – it is self-evident that prohibitive pricing will produce a general disincentive to purchase all of the required lenses, as well as care products if wearing reusable lenses, and to use them as required. The contact lens care industry thus has an obligation to contain prices as far as economically possible.
2. Product support – clear and unambiguous packaging and simple and clear instructions are thought to be important contributing factors to compliance enhancement; such issues are the sole responsibility of the contact lens industry. Many companies provide attractive reusable lens starter packs that motivate patients.
3. Research and development – contact lens care systems should be designed to be effective, as distinct from the usual practice of designing systems that are merely efficacious. An efficacious system is one that can be demonstrated to work under ideal situations – that is, assuming full patient compliance. An efficient system is one that will work in a 'real-world' scenario, allowing for a certain level of non-

compliance. This chapter has established that full compliance does not exist. All patients will be at least partially non-compliant in some aspect of their care regimen. If one accepts this argument, then it behooves the contact lens industry to develop effective contact lens care systems.

Conclusion

Patient compliance with contact lens wear and care is a complex issue; it is difficult to enhance and predict. As a result, we must continue to rely on the outcome of research and models such as those discussed in this chapter. Practitioners are invited to contemplate all of the issues highlighted in this chapter when faced with adverse ocular reactions to contact lens wear; although the patient may well be at fault, it is important to avoid taking the easy option of 'blaming the victim'!

Access the complete references list online at http://www.expertconsult.com.

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43

Practice Management

NIZAR K HIRJI

Introduction

Contact lens practice by definition resides within an optometric practice embracing, amongst other products and professional services, the prescribing, fitting and dispensing of contact lenses and associated products and professional services. Thus, practice management issues that have an impact on contact lens practice are firstly all those that have an impact on an optometric practice, and additionally, if it is possible to separate them, those issues that are regarded as more the domain of contact lens practice.

Practice management may be defined as that activity concerned with planning, organizing and controlling the non-clinical activities of an optometric enterprise to ensure predefined outcomes and goals, through the effective use of the available physical, financial and human resources. The supply of optometric goods and professional services ranges from very tangible goods (e.g. supply of a contact lens case) to entirely intangible professional services such as a contact lens consultation (e.g. aftercare).

In managing the contact lens professional 'service product', for want of a better descriptor, it is important to appreciate that what is involved is primarily the provision of professional services. A detailed description of the characteristics that separate a professional-service-oriented business such as a contact lens practice from a product-oriented business is beyond the scope of this chapter and is detailed elsewhere (Hirji, 1999). These characteristics place special management demands on optometric and contact lens practices.

The key elements that determine the management issues in a primarily service-oriented enterprise such as a contact lens practice can be categorized according to the following six Ps:

1. Practice location and accommodation
2. Personnel at the practice
3. Products and professional services provided
4. Pricing – fees and charges
5. Promotional issues
6. Processes.

These issues have to be considered within the framework of the wider legal, political, economic and institutional environment within which optometry has to operate. This chapter will thus confine itself to a limited overview of these issues. The model adopted here will be that of a contact lens service being provided within optometric practice. It is recognized, of course, that contact lens practice can be effected in a variety of settings, such as medical practices, hospitals and optical dispensing outlets. Nevertheless, the principles of efficient management highlighted here can be applied to all of these situations.

Practice Location and Accommodation

In contact lens practice, the patient participates, in person, in the buying process. It is therefore important for the practice to be located as conveniently and as 'close' to the patient as possible. The decision regarding the location of the practice is crucial, not only in terms of the ease of access for potential patients and customers, but also because a wrong or a poor decision cannot easily be reversed – unlike decisions on pricing or product choice. The costs of a mistake include financial losses involved in acquiring and running a practice (e.g. fixtures and fittings, launch costs) and – just as important to many businesses – the indirect cost of not keeping a competitor out of a better location. The suitability of a particular practice location is based on the estimated potential for attracting patients and customers in a given catchment area and the location of competitors.

Sophisticated models using a variety of information, including census data, family expenditure surveys and geodemographic characteristics, have been developed to help quantify catchment areas and the desirability of differing sites. Checklists with key considerations listed may also be used to help the decision-making process with or without computer modelling. Other good sources of information about an area include local authorities (e.g. planning department, electoral office, rating office, clerks' office), estate agents and the local and national press. Having decided on the location, it is important to ensure that the physical site will be able to accommodate a contact lens practice, including a waiting area, consulting and data collection rooms, spectacle and contact lens dispensaries, staff room, storage / stock room and washrooms.

LAYOUT

The layout of the practice will be governed by the physical limitations of the site and the sequence and order of activities that the patient undergoes during a visit to the practice. Fig. 43.1 illustrates the principal integrated activities of an optometric practice with contact lenses as part of the product / professional service range.

RECEPTION AREA AND FRONT DESK

This is the first person contact position for the visiting patient, and should be a welcoming point as well as a help desk. The reception area will also often be the last point of contact before the patient leaves the practice.

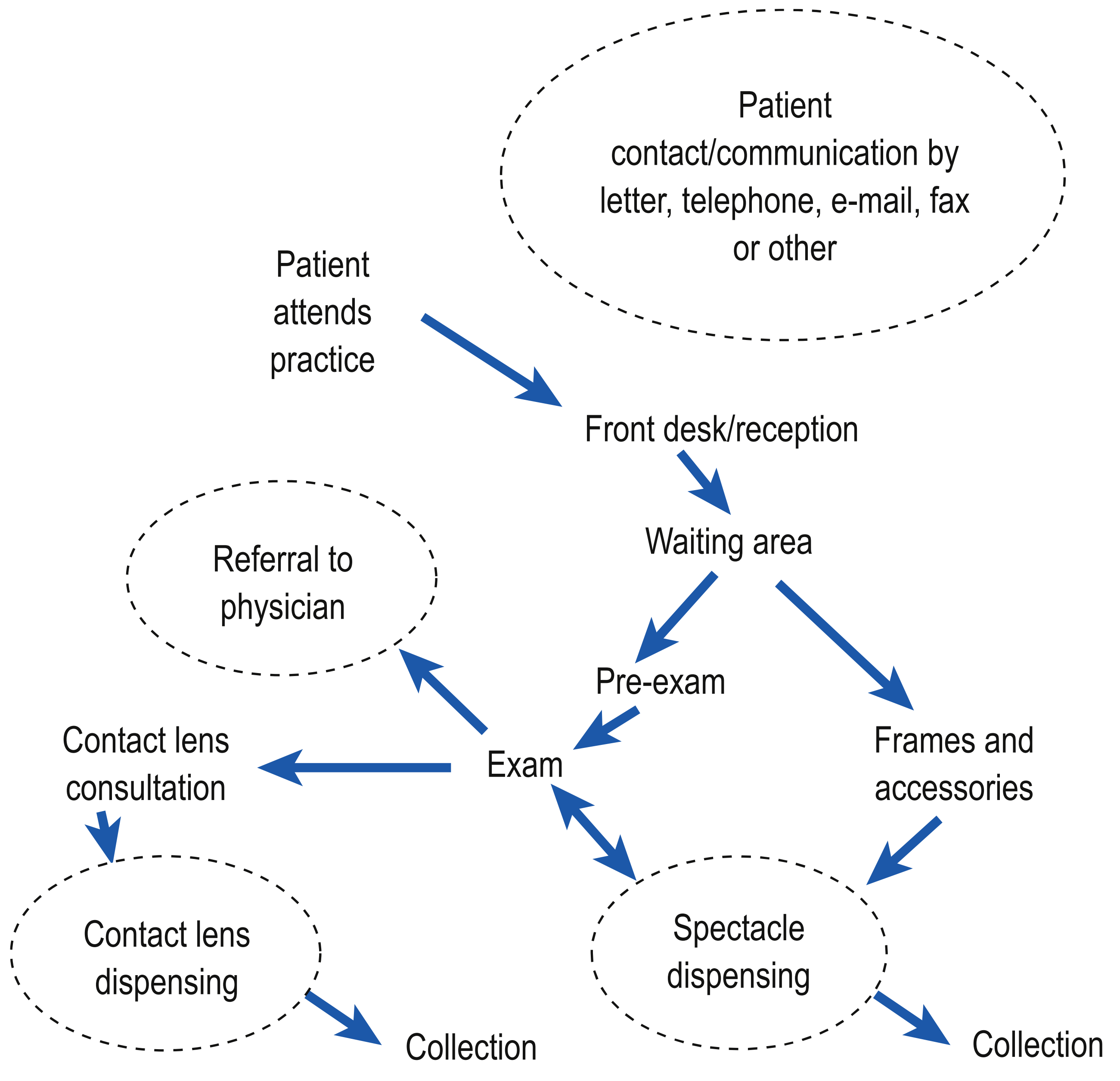

Fig. 43.1 Activity and information flow in contact lens practice.

WAITING AREA

The waiting area needs to be comfortable, with sufficient seating to accommodate potential patients and customers. A rule of thumb worth considering is that this area should be furnished and decorated to be just marginally 'better' than the 'front room' of the patients and customers attending the practice. This is based on the premise that is decorated and furnished below the standards of the 'front room' of the patients attending the practice may impart a negative image, whereas a significantly better décor and furnishing may give the impression that the practice may be 'expensive'.

CONSULTING ROOM

Depending on the patient workload of the practice, more than one room may be dedicated to the consultation and examination activity. Increasingly, delegation of data collection tasks (e.g. non-contact tonometry, visual field analysis, autorefraction, digital photography, optical coherence tomography, etc.) to trained support staff means that an area or room will be utilized for this pre-exam screening or adjunct data collection.

The consulting room will have all the equipment found in a modern optometric practice with an emphasis on anterior-eye evaluation / recording. In addition to this, it will be necessary to have some contact lens verification equipment, and if a speciality practice, possibly a corneal topographer. The need for specialist diagnostic fitting sets and materials (e.g. preformed rigid scleral lenses, bifocal lenses, eye impression materials) will be dictated by the profile of patients attending the practice.

SPECTACLE DISPENSARY

Every contact-lens-wearing patient is an optometric patient who happens to be using contact lenses. All contact lens wearers require spectacles. The spectacle dispensary should thus be able to provide for the functional and aesthetic needs of the patient, just as any optometric practice would.

CONTACT LENS DISPENSARY

The contact lens dispensing area is where patients will attend for instructions and practise of placement and removal of contact lenses onto and from their eyes (see Chapter 38). It is also here that patients will receive their (starter) contact lens care systems where applicable, and advice on wear, care and hygiene with respect to their contact lenses, and will complete the paperwork. It should therefore have the furniture, facilities, materials and equipment to allow this to happen effectively. Employing videos (including streaming videos from the practice website) and CD-ROMs in this area to support the education process along with written materials is now common practice.

Personnel at the Practice

Contact lens practices rely on individuals to deliver their professional services and products to patients and customers. Thus, at a minimum level of practice activity, it will be necessary to employ someone to provide reception and general administrative support with respect to the day-to-day activities of the practice. At the other end of the spectrum, a busy large practice in a shopping centre location may employ additional optometrists, dispensing staff, contact lens hygienists, technicians, optical receptionists / advisors, secretaries and cleaners. It is important to remember that many more individuals will need to be employed to cover the practice requirements in terms of hours per day, particularly as part-time employment increases. The issues of managing the practice staff take increasingly more prominence as the size and the activity of the practice increase (ACAS, 1994).

RECRUITMENT AND SELECTION

Once a vacancy has been identified, and additional hours of staff time are justified, it is essential to establish the duties of the new member of staff. Having decided the qualifications, training needs and skills that are required to do the job, it is useful to prepare a job description or profile and then to decide on the type of person who would ideally be recruited to fill this vacancy – that is, a person specification. Two good methods of producing the specification include Roger's seven-point plan (Roger, 1951), taking account of:

1. physical make-up
2. attainments
3. general intelligence
4. special aptitudes
5. interests
6. disposition
7. circumstances.

Also Fraser's five-point grading (Fraser, 1958), which covers:

1. impact on others
2. qualifications or acquired knowledge
3. innate abilities
4. motivation
5. adjustment or emotional balance.

Table 43.1 describes an example of a person specification for a receptionist in a practice that wants to develop a contact lens interest.

Selection then involves choosing the right person by interviewing short-listed candidates with a view to

TABLE 43.1 Example of a Person Specification – Fraser's Fivefold Grading

Essential Qualities	Desirable Qualities
1. IMPACT ON OTHER PEOPLE (appearance, speech and manner)	
Clean and tidy presentation	Smart presentation
Good writing and speech	Gets on well with young adults
2. QUALIFICATIONS AND EXPERIENCE (education, training and work experience)	
GCSE English and mathematics	Experience in medical reception or pharmacy
Able to work on a computer	Experience of data input and output
3. INNATE ABILITIES (aptitude for learning)	
Quick to grasp ideas and views	Able to prioritize and decide on action
4. MOTIVATION (consistency, determination and success in achieving goals)	
Interested in health care and general cosmesis	Interested in a potential career in optics
5. ADJUSTMENT (emotional stability, ability to handle stress and ability to get on with people)	
Friendly and able to work as part of a team	Comfortable with the pressures of day-to-day practice activities and the demands of patients and practitioners

(Adapted from Hirji, N. K. (1999). Business Awareness for Optometrists – a Primer. Oxford: Butterworth-Heinemann)

selecting the applicant who has the skills, abilities, aptitude and personal qualities to do the job. The job description and the person specification will decide the major selection criteria normally considered during the interview process.

CONTRACT OF EMPLOYMENT

A contract of employment is simply the legal agreement between the employer and the employee, clarifying their mutual obligations. The law in most countries provides the employee with a number of employment rights and imposes some statutory obligations on the employer. Contracts do not have to be in writing. However, employment law in the UK has gone slightly further: even where a verbal contract may exist, there is a requirement for employers to give any employee taken on for 1 month or more a written statement setting out the main employment particulars within 2 months of the starting date of employment. Covered by common and contract law, contracts of employment are governed by the Employment Rights Act (1996).

DISCIPLINE AND DISMISSAL

A practice handbook that sets out basic information about the policies and facilities of the practice can act as a clear guide for all staff to providing optometric and contact lens services. It should be an easily accessible set of ground rules that promote a good working environment in the practice. If a case of misconduct (breach of rules that merits disciplinary action) arises, the rules in the handbook will be invaluable as to the expected conduct. Table 43.2 gives an outline disciplinary procedure.

TRAINING STAFF

Training embraces the identification and development of employee potential for job satisfaction, improvement, practice value creation and ultimately improved patient care. It can often be the driver of improvements and has the potential to bring about reduced costs, increased value and practice profitability. Ultimately, training is about getting people to do different things or to do things differently.

For training to be effective for a contact lens practice, however, it must be:

- valid – relevant to contact-lens-related jobs in the practice
- capable of solving problems – identified as needing resolution in practice
- focused on objectives – either at the individual or at the job / practice level
- measurable – its results can be gauged directly or indirectly.

Improvements that training and development bring should hopefully result in reduced costs and increased value and profits through the following (for example):

- Improved efficiency – doing the job correctly, accurately and with care at the outset reduces replacements, unplanned rescheduling and revisits to the practice by patients. This improves utilization of resources and practice output overall.
- Improved quality – this enhances the reputation of the practice, and reduces complaints, costs of returns, refunds and credits.
- Less wastage and reworking – not only is the material not wasted, but also there is a greater cost saving in staff costs, time the equipment is occupied and ancillary costs in reworking the job by the laboratory (e.g. a complete pair of spectacles, alternative set of contact lenses).
- Improved consulting room and equipment utilization – consulting room occupancy and equipment use dictate the capacity of the practice to conduct eye exams and contact lens consultations. An unnecessarily occupied or indeed unoccupied consulting room is costly.
- Reduced time taken to do jobs – less time taken to produce the same or better-quality products will translate to reduced staff costs relative to sales revenues.
- Improved time management – translates to improved patient scheduling and staff usage, which will lead to reduced staff costs relative to sales revenues.
- Reduced staff turnover – costs of recruitment, selection, training and reduced efficiency are reduced.
- Reduced accidents and equipment down-time – this reduces costs to the practice in terms of costs of sick pay, down-time of equipment, compensation claims, insurance premiums, unscheduled service costs and replacements.
- Reduced sickness and absenteeism – greater job satisfaction means better staff morale and efficient teamwork.

Training alone is not the driver of these benefits. Other factors that affect these issues include economic, political and employment situations locally and nationally.

TABLE 43.2 Outline of Disciplinary Procedures

Offence	Action	Details
Minor misconduct	Verbal discussion (informal)	Counsel and help employee improve Keep a note
Minor misconduct	Stage 1 Verbal warning (formal)	Advise of reason for the warning Advise that this is a first stage of the disciplinary procedure and the right of appeal Keep a note of the warning for, say, 6 months and then repeal subject to satisfactory conduct and performance
Repeated minor misconduct or serious misconduct	Stage 2 Written warning	Advise of reason for warning Give details of the improvement required and the timescale Advise that this is the second stage of the disciplinary procedure and the right of appeal Keep a note of the warning for, say, 6 months and then repeal subject to satisfactory conduct and performance
Repeated minor/serious misconduct or gross misconduct – in which case suspension with pay may be invoked until investigation is completed	Stage 3 Final written warning	Advise of reason for warning Explain that dismissal will occur if there is no satisfactory improvement Advise of the right of appeal Keep a note of the warning for, say, 12 months and then repeal subject to satisfactory conduct and performance
	Stage 4 Dismissal	Give the reason for dismissal Give the date of termination of employment Advise of the right of appeal

(Adapted from Torrington, D. & Hall, L. (1987). Personnel Management – a New Approach. New Jersey: Prentice-Hall, and ACAS (1994). Employing People – The ACAS Handbook for Small Firms. London: ACAS Publications.)

An important decision for the practice owner–manager is to decide what training can be done by the practice itself and what external support will be required. It is not unusual for contact lens/ophthalmic product suppliers to support their customers in this regard.

Products and Services Provided

Income generated in an optometric practice is derived from provision and sales of:

- Eye examinations and other professional services – the vast majority of patients in an optometric practice attend for eye examinations, which is the key value driver. Only after a complete eye exam is conducted are contact lenses normally prescribed and dispensed. Therapeutic privileges are now available to optometrists in many countries (often requiring appropriate postgraduate training) and this service will also contribute to the income of the practice.
- Spectacle dispensing – regardless of how much contact lens activity a practice has, the supply of complete spectacles will always be a necessary part of contact lens practice.
- Contact lenses – apart from a stock of 'off-the-shelf' designs, the practice may need to have to hand specialist contact designs and products.
- Accessories – a range of appropriate contact lens care systems and other accessories need to be available, such as sunglasses, spectacle chains, contact lens and spectacle cases.
- Subscription schemes – both contact lens wearers and spectacle-wearing patients benefit from service agreement schemes, which enable them to obtain replacement products and specific professional services at preferential terms. Such schemes are now common and maintain a degree of continuity to the practice.

Pricing – Fees and Charges

The very personal and individual nature of both services and products involved in contact lens practice means that mass production approaches cannot be applied without risking negative effects to the practice. When making pricing decisions, three elements normally need to be taken into account: the practice cost base, the patients and customers to the practice, and the competition. The fees and charges of the practice will generally be a compromise between what the business needs to cover costs, what the patients and customers expect to pay for the services and the products, and what the competition charges. Pricing issues are further confounded by the fact that not every owner–optometrist will seek to maximize profits, nor is detailed information about costs, competition and the potential patient/customer easily available to the practice.

SPECIALITY–COMMODITY CONTINUUM

The concept of the speciality–commodity continuum applies to both contact lens products and services. At one extreme is the service product, consisting of a speciality service that is highly differentiated from the rest of the competition, whilst at the other extreme is a commodity.

Fig. 43.2 illustrates this speciality–commodity continuum as a conceptual map, describing some of the characteristics of the competition, gross profits, price differentiation and image differentiation associated with the two extremes.

Optometric practices would be best served by ensuring that contact lens products and services do not slide to the extreme commodity end. It is worth noting that the features of a commodity, which include: self-determination of need, self-management of use, non-invasive with little (perceived) potential for harm, non-regulated and price determined by market forces.

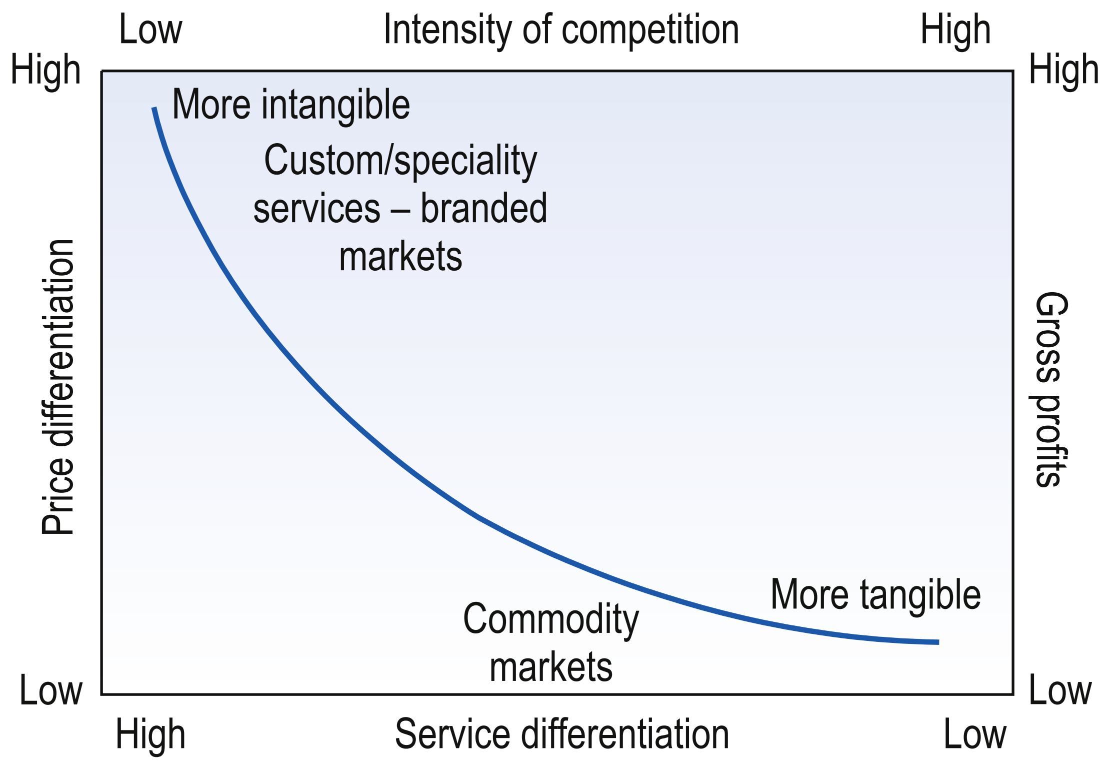

Fig. 43.2 The speciality–commodity continuum.

PROFESSIONAL MODEL

Developing a fees and charges schedule is never an easy task. Once one subscribes to the need to move away from the commodity end of the market, where competition relies primarily on purchase decisions based only on price, to the speciality end then the need for a professional model for fees and charges becomes paramount. One way to do this is to establish the expenses overhead per hour for the practice (chair time). Knowing the actual chair time required for differing types of contact lens services (e.g. spherical rigid lenses, soft lenses, daily/ monthly disposable soft lenses, toric and bifocal lenses), allowing for potential unscheduled visits, adding the contact lens material and care system costs (duly marked up, say 20–35%), and any other handling charges, this figure can then be used to calculate the fees and charges for any service product provided by the practice. With the advent of mail-order contact lenses, internet trading and an increasing trend for contact lenses to be considered as a commodity, it is important to adopt a transparent fees and charges schedule that is competitive on a like-for-like basis without eroding the professional fees dimension.

Promotional Issues

Communicating the availability of products and services that have been identified as 'needs and wants' by patients and customers, at a price that creates sustained value for the practice, is what promotions are about. A variety of options are open to the optometrist–owner to communicate with existing and potential contact lens patients and customers. The mix of these will often be determined by which stage the practice is at in its life cycle. For example, a new practice with mostly new patients will rely more on external promotions, whereas an existing mature practice will rely more on internal communications and promotions.

INTERNAL

Internal promotions embrace all aspects of communication to existing contact lens patients and include the spectrum from personal contact at the practice – which embraces the practice ambience and point-of-sale literature – through to special mailings. Personal communication is by far the most significant mode of internal contact with the patient, and can adopt the following guises:

- The recall letter – with careful database management, it is possible not only to send out recall letters for routine contact lens aftercare visits, but also to tailor promotions of specific products and services to patients by criteria other than clinical need.
- Special mailings – some practitioners will send patients thank you cards for referrals and cards on the arrival of a new family member.
- Practice newsletters – both via conventional mail and by e-mail – are increasingly used and are indeed a good way of educating and maintaining contact with patients, and keeping them aware about the practice, its personnel and its activities.

The use of a website as an internal communication tool merits some mention. Practice websites, and electronic mail, will increasingly play a role in allowing patient education, email recall letters, e-promotions and opportunities for patients to contact the practice to order sun wear, contact lens accessories and replacement products, to book an appointment and even to submit medical history. Similarly, it makes sense to consider a contact lens aftercare appointment reminder communication via email or SMS.

EXTERNAL

These promotions include all activities where potential contact lens patients might be exposed to the activities, personnel or products at the practice. These include national and regional newspapers, trade and professional magazines, radio and television broadcasts, telephone directories, exhibitions and health fairs, direct mail, public relations, speaking engagements and the worldwide web. This last method enables practices to broaden their catchment area, offer sun wear, contact lens accessories, frames and spectacles along with practice information and opportunities to book appointments online.

Processes

These are the procedures, mechanisms and routines that the practice adopts to provide the services and products to patients and customers. Although in contact lens practice the people element is critical, no amount of attention and effort from staff will overcome unsatisfactory process configuration. For example, no matter how well members of staff do their job – or what equipment one uses for the data collection – if the process of, say, booking appointments is too cumbersome or inaccurate then patient dissatisfaction is inevitable, as is ineffective clinical care. Generally, the greater the complexity and divergence (variability of the steps/ sequences) of the task, the more it is usually necessary to empower the staff to exercise their judgement in the best interest of the patient and the practice.

A variety of processes are employed in managing patients, products, money and personnel. They are too numerous to include in full, so a selection of key contact lens activity-oriented processes is mentioned here.

MANAGING PATIENTS

Patients who attend for contact lens services have requirements in addition to their needs as routine optometric patients, and will thus place special demands on the processes of the practice. These range from appointment scheduling through to the transfer of records and clinical details.

CONTRACTS, SERVICE AGREEMENTS AND INFORMED CONSENT

A contract is an agreement between parties (two or more) that is enforceable by law. Four essential elements need to be present for a contract to be legally enforceable; specifically, there must be:

1. the existence of both an offer and an acceptance
2. an intention by both parties to create a legally enforceable relationship
3. clear and certain terms and conditions, for the courts to be able to enforce them
4. consideration – that is to say, each party has agreed to contribute to the deal – for example, the practitioner promises to provide agreed professional services to the patient, such as eye examination, contact lens fitting, supply and aftercare, and the patient in turn promises to pay the agreed fees.

In an attempt to clarify the terms and conditions, to educate the patient and to generate documentary evidence, practitioners have produced a variety of contact lens service / subscription agreements and policy documents. These generally range from describing what is included in the fees and charges, to what is included in prepaid contact lens service subscriptions (for regular optometric and contact lens reviews and replacement of contact lenses).

Contracts, such as those mentioned above, do not have to be in writing. They can be verbal, as long as the above elements are present and enforceable by the law (in theory). However, in practice it is a real challenge without written documentation.

The doctrine of informed consent is an aspect of health care generally that is constantly evolving, and arises from the fact that touching another person (during an optometric consultation) without consent may be regarded as offensive or harmful, for which damages could be claimed and awarded. In medicine this has often translated to mean consent to medical procedures. In reality, it is an approach to practising defensively, and if a claim of negligence arises, it could be shown that the patient knew and consented to what was done, as a potential means of defence. Although the USA has adopted an approach whereby the fullest possible information as to the treatment / procedure is given to the patient to make informed choices, the English courts tend to look at approved practice amongst professionals when deciding what the patient should be told of the risks / procedures. Nevertheless, it would be prudent to keep patients as well informed as is reasonably possible, to ensure long-term success in contact lens practice.

PATIENT SCHEDULING

The eye examination is the key value driver in any optometric practice, whilst staff costs are the key costs. Effective practice resource management without compromising clinical care is often dependent on the use of appropriate appointment scheduling methods. There are three principal approaches commonly found in practice:

1. Traditional – patients here are booked in at regular intervals with equal times set aside for each consultation. For example, patients are booked in every 20 minutes, starting and ending at a given time. It is simple and that is why it is used so often. However, it does not allow for patients who require longer consultations or patients who require less time. It is thus possible to end up with unproductive portions of time when less time with a patient is needed, and long waiting queues if a patient requires a longer consultation.
2. Block system – this is not often used in optometry but is found in hospitals and general medical practice. This method involves scheduling multiple patients in the same time slot. For example, there would be three patients booked at 9.00 a.m. and then none until 10.00 a.m., when there would be three more patients booked, and so on. Individuals who have experienced this approach are often disgruntled to find that they have the same appointment slot as others.
3. Mixed – some practices find a mixture of traditional and block booking to be a workable combination, using the block system for scheduling shorter 15-minute visits (e.g. groups of children, some contact lens follow-up visits) and 20-minute scheduling for routine eye exam consultations.

The challenge is to schedule patients so that the down-time and the time taken to 'settle in' in the consulting room do not curb the consultation time of the practitioner. In contact lens practice, appointments are normally scheduled for eye examinations, preliminary examination and initial fitting, evaluation after diagnostic lens wear (return), collection / hygiene, routine aftercare and unscheduled visits (urgent, emergency).

PATIENT EDUCATION

Contact lens practice has a particular responsibility to instruct patients on the wear, care and hygiene with respect to contact lenses. Anyone who has been in contact lens practice will concur that good patient education is key to successful contact lens wear. It is thus not surprising that significant resources are often dedicated to this function in contact lens practice. This may include a dedicated area / room, and a dedicated and appropriately trained individual (contact lens hygienist) to instruct and educate one or more patients at a time on placement and removal of lenses, wearing schedules, caring for lenses and cases, general hygiene and lid hygiene. It is also in this area that any service agreements and details of emergency cover are discussed and issued. Increasingly, practices provide both verbal and written instructions, and some also lend videos and CD-ROMs for patients to view and review the procedures in their own home. It is logical for this information to be made available and downloadable from practice websites for patients.

RECORDS ON PATIENT WEB PAGES

The internet has already significantly altered the way in which one can promote contact lens practice. Practice websites carrying information and offering access to the supply of contact lenses and other optical products online directly to patients are already here. This is an expected reaction to counter mail-order and online supply of optical products by non-optometrists and non-opticians. However, from a patient perspective, it is worth bearing in mind that the internet also offers the possibility to store personal medical and associated records in one easily accessible location ('cloud' storage). This would then enable any health-care practitioner, anywhere in the world, to access these records with the consent of the patient and protected by using an appropriate password. It is thus not too far-fetched for patients to ask that their contact lens/optometric data be uploaded to their personal health web pages in the future.

MANAGING CONTACT LENS PRODUCTS

The tangible products that contact lens practices supply include all those products normally supplied in general optometric practice, plus contact lenses, contact lens care systems and associated products. In view of recent concerns about the transmission of new-variant Creutzfeldt–Jakob disease (see Chapter 17), the use of empirically fitted rigid lenses is now the preferred option, and the use of stock disposable soft and silicone hydrogel lenses a practical alternative. It is thus necessary for contact lens practices to stock a variety of lens types for fitting and possibly initial supply. However, it must be borne in mind that this stock, if paid for by the practice, is creating value only if sold. Similarly, the stocking of a variety of contact lens care systems and accessories is essential in providing a complete service. Like contact lenses, stock that is held in the practice creates value only if it is sold or supplied to patients and customers. Bar-coding of contact lenses and care systems will help manage the inventory of both contact lenses and solutions; however, the value of this process in the absence of a standardized bar-coding scheme is somewhat limited.

MANAGING MONEY

Income to the practice will accrue from patients, customers and third-party payments (national and private health insurance, driving licence authorities, employers). It is therefore important that records are kept of every transaction and that there is no hindrance to receiving these payments by any method (e.g. cash, credit cards, cheques, direct debit, standing order, electronic transfer of funds) (Holmes and Sugden, 1986). Of these methods, the use of direct debits in prepaid subscription schemes has proved to be a particularly useful option. Similarly, the practice will need to pay its suppliers (e.g. laboratories, prescription houses, various forms of sales tax, telephone, printing and stationery) and its staff.

The provision of contact lens services, like optometric services, is indeed a provision of professional time. The supply of products is secondary to this, and it is appropriate to adopt an accounting method that mirrors this approach. The Association of Optometrists in the UK has published guidance on such an approach and the reader is referred to this (Hayes et al., 1999).

The use of computers in practice management and in particular practice finances is beyond the scope of this chapter. Suffice it to say that many 'off-the-shelf' software options are available and adaptable, whilst others dedicated to optometric practice management and incorporating the special needs for contact lens practice are also available. Fig. 43.3 illustrates practice activity where computers may be utilized.

LENS ORDERING

A majority of lenses prescribed today are obtained initially from in-office inventories of disposable lenses. Once the patient is satisfied with the lenses fitted, an order must be placed with the manufacturer, or a third-party distributor, for an appropriate ongoing supply (typically for 3 or 6 months). There is clearly a wide assortment of technical means of placing an order, which parallels modes of modern communication – that is, a written order posted in the mail (rarely used these days), telephone, fax and the internet. The latter two modes of communication are preferred because there is less likelihood of confusion, and a clear audit trail for checking, if the order is issued in textual form. Patients are often looking to order replacement lenses online. If patients were able to do this from a practice website, patient retention would be likely to be enhanced (McNelis, 2009).

Disposable soft lenses are typically specified by manufacturer, lens tradename and lens power. If the lens is available in a variety of parameters, then the parameter of choice obviously needs to be specified also. More-detailed information is generally required for custom-made soft lenses and rigid lenses. As a general rule, the more details that are supplied when ordering a custom-designed lens, the greater is the likelihood that the lens delivered will be as required.

Professional Regulation

The manner in which a practitioner fits and supplies contact lenses may be controlled by various regulations. In the UK, the General Optical Council (GOC), by the powers vested in it by the Opticians Act 1985 section 31, has made rules regulating the prescription, supply and fitting of contact lenses by registered optometrists, opticians or companies and their employees.

The Rules on the Fitting of Contact Lenses 1985 cover the details with respect to the circumstances in which trainee optometrists or opticians may fit contact lenses. The Contact Lens (Qualifications etc.) Rules 1988 provide for a minimum level of education, training and qualification before a registered optometrist or optician can undertake the fitting of contact lenses in the UK. The Contact Lens (Specification) Rules 1989 require that an optometrist or optician who fits contact lenses shall on completion of the fitting give the patient a written specification of the lenses in sufficient detail to enable the lens to be replicated.

The Opticians Act 1989 (Amendment) Order 2005, made under section 60 of the Health Act, 1999, amends the Opticians Act 1989 and came into effect with its supporting Rules on 30 June/1 July 2005. This was the first of the series of orders that the government made to modernize the health-care professions in the UK and it significantly affects the provision of optometric and optical care and the framework within which the optical professions practise and optical businesses operate (Hirji and Clarkson, 2006). This order improves significantly the way in which the GOC can discharge its duty of protecting the public by bringing about the changes that affect registration, recognition of specialisms, professional indemnity insurance, continuing education and training, and registrants' fitness to practise and supply contact lenses, and it allows the GOC to seek additional relevant information about the registrant, including character. It redefines the role of the GOC as the overseer of 'professional education, conduct and performance among registrants'.

All contact lens fitting and aftercare remain entirely the domain of registered practitioners, including the fitting of zero-powered contact lenses (plano cosmetic lenses), which when completed obliges the practitioner to provide a specification of the contact lenses prescribed (subject to the Data Protection Act 1988), which has to include the following information (SI 2005/1481):

- the name and address of the patient
- if the patient has not attained the age of 16 on the day the specification is issued, his/her date of birth

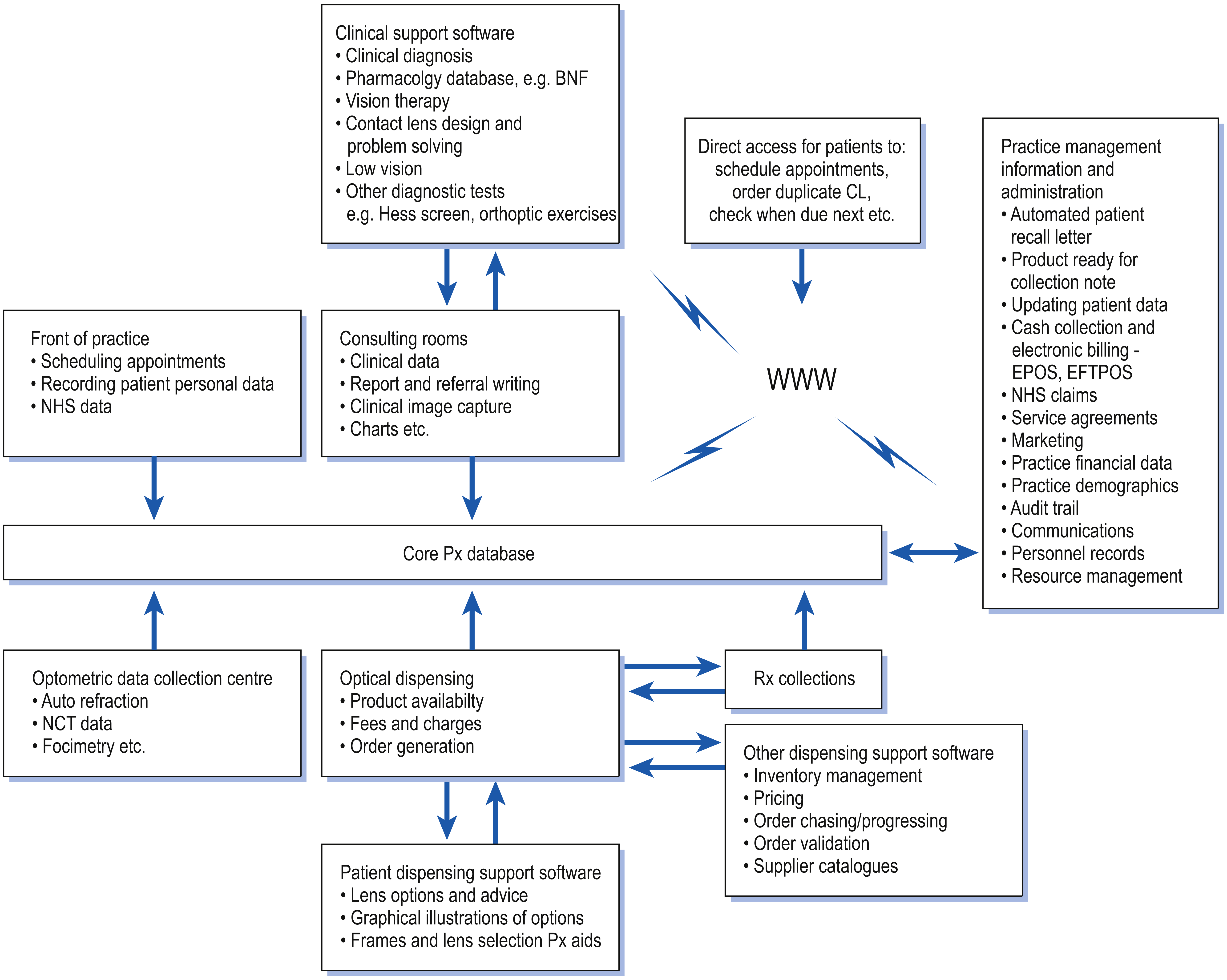
Clinical support software
• Clinical diagnosis
• Pharmacolgy database, e.g. BNF
• Vision therapy
• Contact lens design and problem solving
• Low vision
• Other diagnostic tests e.g. Hess screen, orthoptic exercises
Direct access for patients to: schedule appointments, order duplicate CL, check when due next etc.
Practice management information and administration
• Automated patient recall letter
• Product ready for collection note
• Updating patient data
• Cash collection and electronic billing - EPOS, EFTPOS
• NHS claims
• Service agreements
• Marketing
• Practice financial data
• Practice demographics
• Audit trail
• Communications
• Personnel records
• Resource management
Front of practice
• Scheduling appointments
• Recording patient personal data
• NHS data
Consulting rooms
• Clinical data
• Report and referral writing
• Clinical image capture
• Charts etc.
WWW
Core Px database
Optometric data collection centre
• Auto refraction
• NCT data
• Focimetry etc.
Optical dispensing
• Product availabilty
• Fees and charges
• Order generation
Rx collections
Other dispensing support software
• Inventory management
• Pricing
• Order chasing/progressing
• Order validation
• Supplier catalogues
Patient dispensing support software
• Lens options and advice
• Graphical illustrations of options
• Frames and lens selection Px aids

Fig. 43.3 Practice activity where computers may be utilized. BNF = British National Formulary; CL = contact lens; EPOS = electronic point of sale; EFTPOS; electronic funds transfer at point of sale; NHS = National Health Service; Px = patient; Rx = prescription; NCT = non-contact tonometry. (Adapted from Hirji, N. K. (1999). Business Awareness for Optometrists – a Primer. Oxford: Butterworth-Heinemann.)

- the name of the practitioner and his/her registration number in the GOC register or General Medical Council register
- the address from which the practitioner practises
- the name of the practice on the premises of which the fitting was done
- the date the fitting was completed
- sufficient details of any lens fitted to enable a person who fits or supplies a contact lens to replicate the lens
- the date that the specification expires
- and such information of a clinical nature as that prescribing practitioner considers to be necessary in the particular case.

This closes the loophole that existed for non-registrants to fit and supply zero-powered cosmetic contact lenses prior to this order. However, duplicate contact lenses can be purchased by the public from unregistered suppliers, in person, via mail order or through internet-enabled enterprises as a result of this order, except for:

- minors
- those registered severely visually impaired
- those who are visually impaired

in which case, supply can only be by a registrant.

There are, however, conditions imposed, which include the following: that the transaction is the result of:

- a valid verified original contact lens specification from a registered practitioner, submitted either in writing or electronically
- for the use of the person named in the specification
- before the expiry date mentioned in the specification
- and that the supply is under the direction of a registered optometric/optical practitioner or a medical practitioner.

'General direction' in this context was described during the passage of the legislation through parliament as meaning that a registered practitioner is employed in the management chain of the supplier's business and accountable for what goes on between the supplier and the purchaser, ultimately answerable to the GOC and therefore providing a measure of protection to the public, which was hitherto absent. The seller (whether registered or unregistered) must also make reasonable arrangements for the person who is purchasing the contact lenses from the seller to receive aftercare. The supply of zero-powered cosmetic contact lenses is also covered, by bringing this area under the auspices of the GOC. The supply of contact lenses by suppliers and manufacturers to registrants and others and not directly to patients would not, however, be subject to such requirements. It should also be noted that it remains a defence to any prosecution under the relevant section to demonstrate that the lenses were sold as an antique (except where the seller had reason to believe that the lenses would be used to correct, remedy or relieve a defect of sight) (Hirji and Clarkson, 2006).

On 30 October 2006, the GOC released a statement setting out the GOC's view that, whereas the sale of prescription (sight-correcting) contact lenses may be supplied under the ‘general direction’ of a GOC registrant or a medical practitioner, a ‘supervised sale’ is a requirement for the sale of plano (zero-powered) contact lenses. The statement also affirms the GOC position that a supervisor (a registered optometrist, dispensing optician or medical practitioner) must be able to exercise professional skill and judgement as a clinician. In the absence of any statutory definition of ‘supervision’, however, the GOC will consider the issue of whether a sale was made under ‘supervision’ on a case-by-case basis, involving expert clinical opinion as appropriate. Also, the GOC asked the professional optical bodies to provide a detailed guideline on their interpretation of the meaning of ‘supervision’ (February 2007). Finally, in the press release of the same date, the GOC states that only in the supply of corrective lenses will the purchaser be required to provide a valid ‘specification’ for the supply to be legal (Hirji and Clarkson, 2007). The College of Optometrists and the Association of British Dispensing Opticians now provide guidance on their interpretation of ‘supervision’ (essentially that the practitioner should be in a position to exercise clinical judgement and intervene, and ensure that appropriate aftercare arrangements are made) and of ‘general direction’ (essentially that the practitioner should ensure and be satisfied that procedures are in place to safeguard the patient, that the supplier [person] is appropriately trained, that the lenses supplied meet the specifications and that appropriate aftercare arrangements are made) (College of Optometrists, 2007, 2014). This guidance has been accepted by the GOC.

Conclusion

A key aim of this book has been to describe the great clinical and intellectual challenges involved in contact lens practice. This chapter has outlined the principles involved in managing an eye-care practice that engages in contact lens fitting. By providing an organized and efficient service to patients, and paying proper attention to staff management and support, contact lens practice can be enjoyable and profitable as well as being clinically challenging.

Access the complete references list online at http://www.expertconsult.com.

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OUTLINE

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APPENDIX

A

Contact Lens Design and Specifications

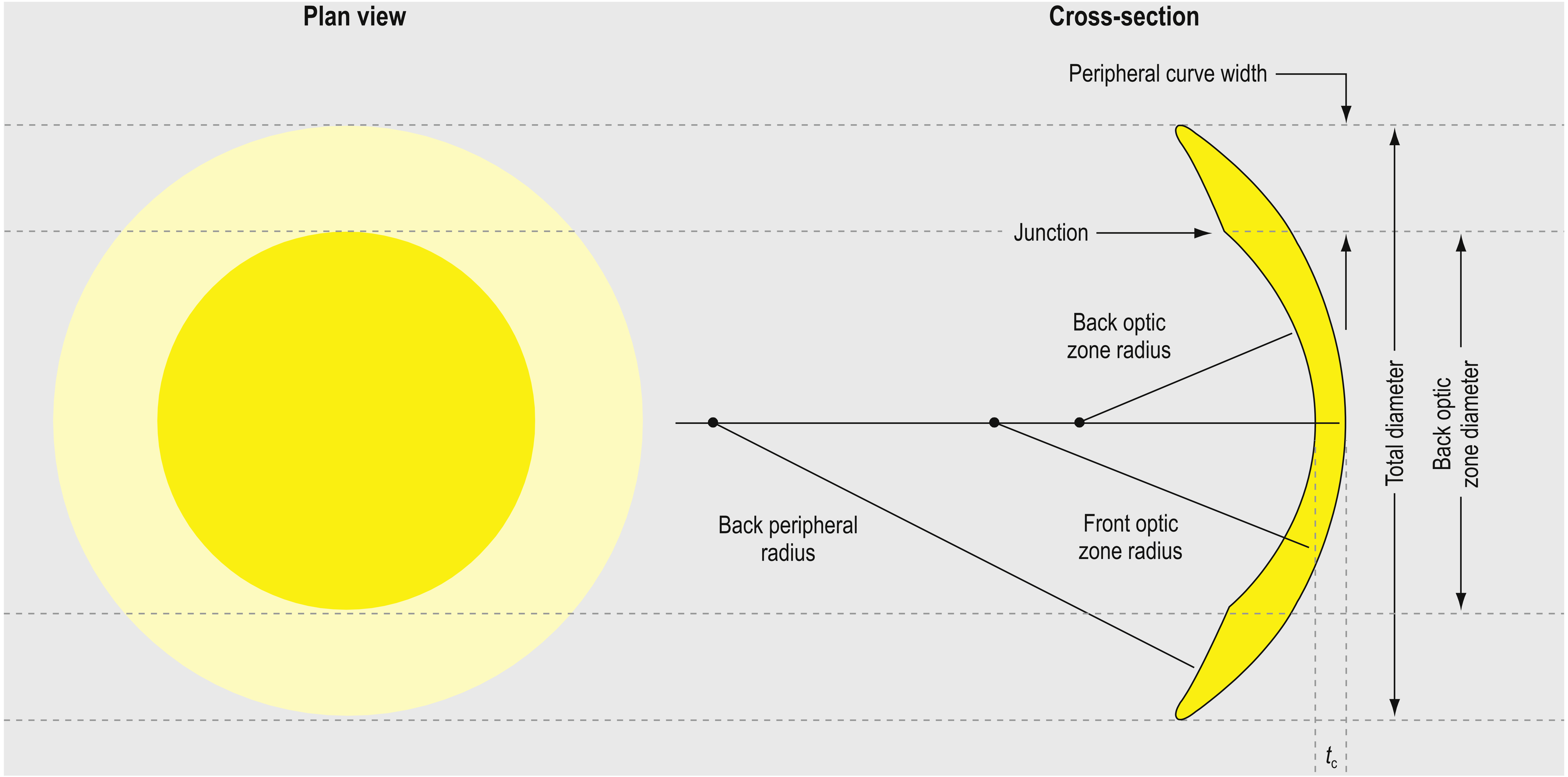

Plan view
Cross-section
Peripheral curve width
Junction
Back optic zone radius
Back peripheral radius
Front optic zone radius
Total diameter
Back optic zone diameter
t_c

Figure A.1 Plan and cross-sectional view of a minus-powered contact lens with a single curve front surface and bicurve back surface.

Terms, Symbols and Abbreviations used to Describe Contact Lenses

Term	Symbol	Abbreviation
Back optic zone radius	r_0	BOZR
Back peripheral radius	$r_1, r_2, \ldots$	BPR1, BPR2, …
Front optic zone radius	r_{a0}	FOZR
Front peripheral radius	$r_{a1}, r_{a2}, \ldots$	FPR1, FPR2, …
Back optic zone diameter	$\varnothing_0$	BOZD
Back peripheral zone diameters	$\varnothing_1, \varnothing_2, \ldots$	BPZD1, BPZD2, …
Total diameter	$\varnothing_T$	TD
Front optic zone diameter	$\varnothing_{a0}$	FOZD
Front peripheral zone diameters	$\varnothing_{a1}, \varnothing_{a2}, \ldots$	FPZD1, FPZD2, …
Geometric centre thickness	t_c	tc
Carrier junction thickness	t_{a0}	tj
Peripheral junction thickness	$t_{a1}, t_{a2}, \ldots$	ta1, ta2, …
Radial edge thickness	t_e	RET
Axial edge thickness	t_{ak}	AET
Radial edge lift	l_r	REL
Axial edge lift	l_a	AEL
Front vertex power	F_v	FVP
Back vertex power	F_v'	BVP
Oxygen flux	j	j
Oxygen permeability	Dk	Dk
Oxygen transmissibility	Dk/t	Dk/t

The terms and symbols outlined above were obtained from the following standard:
ISO 8320–1986 Optics and optical instruments – contact lenses – vocabulary and symbols.
The abbreviations given above were modified from those suggested by:
Hough, T. (2000). A Guide to Contact Lens Standards. British Contact Lens Association.

APPENDIX
B

Contact Lens Tolerances

TABLE A
Dimensional Tolerances for Soft, Polymethyl Methacrylate (PMMA) and Rigid Lenses (all units in mm)

Dimension	Soft Lenses	PMMA Lenses	Rigid Lenses
Back optic zone radius	±0.20	±0.025	±0.05
Back optic zone radii of toroidal surfaces where the difference in radii is:			
<0.20		±0.25	±0.05
0.2–0.4		±0.35	±0.06
0.4–0.6		±0.55	±0.07
>0.6		±0.75	±0.09
Sagitta at specified diameter	±0.05		
Back optic zone diameter	±0.20	±0.025	±0.05
Back peripheral radius		±0.10	±0.10
Front peripheral radius		±0.10	±0.10
Back peripheral diameter		±0.20	±0.20
Total diameter	±0.20	±0.10	±0.10
Front optic zone diameter	±0.20	±0.20	±0.20
Bifocal segment height		−0.10 to +0.20	−0.10 to +0.20
Centre thickness		±0.02	±0.02
Centre thickness, where the nominal value is:			
≤0.10	±0.010 + 10%		
>0.10	±0.015 + 5%		

TABLE B
Optical Tolerances for Soft, Polymethyl Methacrylate (PMMA) and Rigid Lenses

Dimension	Soft Lenses	PMMA Lenses	Rigid Lenses
Back vertex power			
≤5 D		±0.12 D	±0.12 D
≤10 D	±0.25 D	±0.18 D	±0.18 D
≤15 D		±0.25 D	±0.25 D
≤20 D	±0.50 D	±0.37 D	±0.37 D
>20 D	±1.00 D	±0.50 D	±0.50 D
Cylinder power			
≤0.2	±0.25 D	±0.25 D	±0.25 D
2–4	±0.37 D	±0.37 D	±0.37 D
>4	±0.50 D	±0.50 D	±0.50 D
Cylinder axis	±5°	±5°	±5°
Prismatic error (measured at the geometric centre of the optic zone)			
Back vertex power			
≤6 D		±0.25 cm / m	±0.25 cm / m
>6 D		±0.50 cm / m	±0.50 cm / m
Prescribed prism		±0.25 cm / m	±0.25 cm / m

TABLE C
Material Property Tolerances for Soft Lenses

Material Property	Tolerance
Refractive index	±0.005
Water content	±2%
Oxygen permeability	±20%

- The tolerances outlined in this appendix were obtained from the following standards:
  ISO 8321–1: 1991 Optics and optical instruments – contact lenses – part 1: specification for rigid corneal and scleral contact lenses.
  BS EN ISO 8321–2: 2000 (BS 7208–24:2000) Ophthalmic optics – specifications for material, optical and dimensional properties of contact lenses – part 2: single-vision hydrogel contact lenses.
- PMMA tolerances are given here because trial lens fitting sets are often fabricated from this material due to its resilience.
- See also: Hough, T. (2000) A Guide to Contact Lens Standards. British Contact Lens Association.

APPENDIX
C

Vertex Distance Correction

Effective Power (D) of Plus- and Minus-prescription Spectacle Lenses at the Corneal Plane for Various Vertex Distances (mm)

	POWER (D) AT CORNEAL PLANE FOR DIFFERENT VERTEX DISTANCES (mm)									
Spec Rx	8 mm		10 mm		12 mm		14 mm		16 mm	
	Plus	Minus	Plus	Minus	Plus	Minus	Plus	Minus	Plus	Minus
4.00	4.13	3.88	4.17	3.85	4.20	3.82	4.24	3.79	4.27	3.76
4.25	4.40	4.11	4.44	4.08	4.48	4.04	4.52	4.01	4.56	3.98
4.50	4.67	4.34	4.71	4.31	4.76	4.27	4.80	4.23	4.85	4.20
4.75	4.94	4.58	4.99	4.53	5.04	4.49	5.09	4.45	5.14	4.41
5.00	5.21	4.81	5.26	4.76	5.32	4.72	5.38	4.67	5.43	4.63
5.25	5.48	5.04	5.54	4.99	5.60	4.94	5.67	4.89	5.73	4.84
5.50	5.75	5.27	5.82	5.21	5.89	5.16	5.96	5.11	6.03	5.06
5.75	6.03	5.50	6.10	5.44	6.18	5.38	6.25	5.32	6.33	5.27
6.00	6.30	5.73	6.38	5.66	6.47	5.60	6.55	5.54	6.64	5.47
6.25	6.58	5.95	6.67	5.88	6.76	5.81	6.85	5.75	6.94	5.68
6.50	6.86	6.18	6.95	6.10	7.05	6.03	7.15	5.96	7.25	5.89
6.75	7.14	6.40	7.24	6.32	7.34	6.24	7.45	6.17	7.57	6.09
7.00	7.42	6.63	7.53	6.54	7.64	6.46	7.76	6.38	7.88	6.29
7.25	7.70	6.85	7.82	6.76	7.94	6.67	8.07	6.58	8.20	6.50
7.50	7.98	7.08	8.11	6.98	8.24	6.88	8.38	6.79	8.52	6.70
7.75	8.26	7.30	8.40	7.19	8.54	7.09	8.69	6.99	8.85	6.90
8.00	8.55	7.52	8.70	7.41	8.85	7.30	9.01	7.19	9.17	7.09
8.25	8.83	7.74	8.99	7.62	9.16	7.51	9.33	7.40	9.50	7.29
8.50	9.12	7.96	9.29	7.83	9.47	7.71	9.65	7.60	9.84	7.48
8.75	9.41	8.18	9.59	8.05	9.78	7.92	9.97	7.80	10.17	7.68
9.00	9.70	8.40	9.89	8.26	10.09	8.12	10.30	7.99	10.51	7.87
9.25	9.99	8.61	10.19	8.47	10.40	8.33	10.63	8.19	10.86	8.06
9.50	10.28	8.83	10.50	8.68	10.72	8.53	10.96	8.38	11.20	8.25
9.75	10.57	9.04	10.80	8.88	11.04	8.73	11.29	8.58	11.55	8.43
10.00	10.87	9.26	11.11	9.09	11.36	8.93	11.63	8.77	11.90	8.62
10.25	11.17	9.47	11.42	9.30	11.69	9.13	11.97	8.96	12.26	8.81
10.50	11.46	9.69	11.73	9.50	12.01	9.33	12.31	9.15	12.62	8.99
10.75	11.76	9.90	12.04	9.71	12.34	9.52	12.65	9.34	12.98	9.17
11.00	12.06	10.11	12.36	9.91	12.67	9.72	13.00	9.53	13.35	9.35
11.25	12.36	10.32	12.68	10.11	13.01	9.91	13.35	9.72	13.72	9.53
11.50	12.67	10.53	12.99	10.31	13.34	10.11	13.71	9.91	14.09	9.71
11.75	12.97	10.74	13.31	10.51	13.68	10.30	14.06	10.09	14.47	9.89
12.00	13.27	10.95	13.64	10.71	14.02	10.49	14.42	10.27	14.85	10.07
12.25	13.58	11.16	13.96	10.91	14.36	10.68	14.79	10.46	15.24	10.24
12.50	13.89	11.36	14.29	11.11	14.71	10.87	15.15	10.64	15.63	10.42
12.75	14.20	11.57	14.61	11.31	15.05	11.06	15.52	10.82	16.02	10.59
13.00	14.51	11.78	14.94	11.50	15.40	11.25	15.89	11.00	16.41	10.76

Continued

Effective Power (D) of Plus- and Minus-prescription Spectacle Lenses at the Corneal Plane for Various Vertex Distances (mm)* (Continued)

	POWER (D) AT CORNEAL PLANE FOR DIFFERENT VERTEX DISTANCES (mm)									
Spec Rx	8 mm		10 mm		12 mm		14 mm		16 mm	
	Plus	Minus	Plus	Minus	Plus	Minus	Plus	Minus	Plus	Minus
13.25	14.82	11.98	15.27	11.70	15.76	11.43	16.27	11.18	16.81	10.93
13.50	15.13	12.18	15.61	11.89	16.11	11.62	16.65	11.35	17.22	11.10
13.75	15.45	12.39	15.94	12.09	16.47	11.80	17.03	11.53	17.63	11.27
14.00	15.77	12.59	16.28	12.28	16.83	11.99	17.41	11.71	18.04	11.44
14.25	16.08	12.79	16.62	12.47	17.19	12.17	17.80	11.88	18.46	11.60
14.50	16.40	12.99	16.96	12.66	17.55	12.35	18.19	12.05	18.88	11.77
14.75	16.72	13.19	17.30	12.85	17.92	12.53	18.59	12.23	19.31	11.93
15.00	17.05	13.39	17.65	13.04	18.29	12.71	18.99	12.40	19.74	12.10
15.25	17.37	13.59	17.99	13.23	18.67	12.89	19.39	12.57	20.17	12.26
15.50	17.69	13.79	18.34	13.42	19.04	13.07	19.80	12.74	20.61	12.42
15.75	18.02	13.99	18.69	13.61	19.42	13.25	20.21	12.90	21.06	12.58
16.00	18.35	14.18	19.05	13.79	19.80	13.42	20.62	13.07	21.51	12.74
16.25	18.68	14.38	19.40	13.98	20.19	13.60	21.04	13.24	21.96	12.90
16.50	19.01	14.58	19.76	14.16	20.57	13.77	21.46	13.40	22.42	13.05
16.75	19.34	14.77	20.12	14.35	20.96	13.95	21.88	13.57	22.88	13.21
17.00	19.68	14.96	20.48	14.53	21.36	14.12	22.31	13.73	23.35	13.36
17.25	20.01	15.16	20.85	14.71	21.75	14.29	22.74	13.89	23.83	13.52
17.50	20.35	15.35	21.21	14.89	22.15	14.46	23.18	14.06	24.31	13.67
17.75	20.69	15.54	21.58	15.07	22.55	14.63	23.62	14.22	24.79	13.82
18.00	21.03	15.73	21.95	15.25	22.96	14.80	24.06	14.38	25.28	13.98
18.25	21.37	15.92	22.32	15.43	23.37	14.97	24.51	14.54	25.78	14.13
18.50	21.71	16.11	22.70	15.61	23.78	15.14	24.97	14.69	26.28	14.27
18.75	22.06	16.30	23.08	15.79	24.19	15.31	25.42	14.85	26.79	14.42
19.00	22.41	16.49	23.46	15.97	24.61	15.47	25.89	15.01	27.30	14.57
19.25	22.75	16.68	23.84	16.14	25.03	15.64	26.35	15.16	27.82	14.72
19.50	23.10	16.87	24.22	16.32	25.46	15.80	26.82	15.32	28.34	14.86
19.75	23.46	17.06	24.61	16.49	25.88	15.97	27.30	15.47	28.87	15.01
20.00	23.81	17.24	25.00	16.67	26.32	16.13	27.78	15.63	29.41	15.15

*Based on the equation: $OR = SR / (1 - [d \times SR])$, where:
OR = ocular refraction
SR = spectacle refraction
d = vertex distance (m)
The lens powers enclosed within the heavy border relate to the standard vertex distance of 12 mm that will apply in most cases.
(Courtesy of Adrian S Bruce.)

APPENDIX D

Corneal Curvature – Corneal Power Conversion

Conversion between Corneal Front Surface Radius of Curvature (r; mm) and Corneal Power (K; D)

r (mm)	K (D)	r (mm)	K (D)	r (mm)	K (D)	r (mm)	K (D)	r (mm)	K (D)
6.20	54.44	6.58	51.29	6.96	48.49	7.34	45.98	7.72	43.72
6.21	54.35	6.59	51.21	6.97	48.42	7.35	45.92	7.73	43.66
6.22	54.26	6.60	51.14	6.98	48.35	7.36	45.86	7.74	43.60
6.23	54.17	6.61	51.06	6.99	48.28	7.37	45.79	7.75	43.55
6.24	54.09	6.62	50.98	7.00	48.21	7.38	45.73	7.76	43.49
6.25	54.00	6.63	50.90	7.01	48.15	7.39	45.67	7.77	43.44
6.26	53.91	6.64	50.83	7.02	48.08	7.40	45.61	7.78	43.38
6.27	53.83	6.65	50.75	7.03	48.01	7.41	45.55	7.79	43.32
6.28	53.74	6.66	50.68	7.04	47.94	7.42	45.49	7.80	43.27
6.29	53.66	6.67	50.60	7.05	47.87	7.43	45.42	7.81	43.21
6.30	53.57	6.68	50.52	7.06	47.80	7.44	45.36	7.82	43.16
6.31	53.49	6.69	50.45	7.07	47.74	7.45	45.30	7.83	43.10
6.32	53.40	6.70	50.37	7.08	47.67	7.46	45.24	7.84	43.05
6.33	53.32	6.71	50.30	7.09	47.60	7.47	45.18	7.85	42.99
6.34	53.23	6.72	50.22	7.10	47.54	7.48	45.12	7.86	42.94
6.35	53.15	6.73	50.15	7.11	47.47	7.49	45.06	7.87	42.88
6.36	53.07	6.74	50.07	7.12	47.40	7.50	45.00	7.88	42.83
6.37	52.98	6.75	50.00	7.13	47.34	7.51	44.94	7.89	42.78
6.38	52.90	6.76	49.93	7.14	47.27	7.52	44.88	7.90	42.72
6.39	52.82	6.77	49.85	7.15	47.20	7.53	44.82	7.91	42.67
6.40	52.73	6.78	49.78	7.16	47.14	7.54	44.76	7.92	42.61
6.41	52.65	6.79	49.71	7.17	47.07	7.55	44.70	7.93	42.56
6.42	52.57	6.80	49.63	7.18	47.01	7.56	44.64	7.94	42.51
6.43	52.49	6.81	49.56	7.19	46.94	7.57	44.58	7.95	42.45
6.44	52.41	6.82	49.49	7.20	46.88	7.58	44.53	7.96	42.40
6.45	52.33	6.83	49.41	7.21	46.81	7.59	44.47	7.97	42.35
6.46	52.24	6.84	49.34	7.22	46.75	7.60	44.41	7.98	42.29
6.47	52.16	6.85	49.27	7.23	46.68	7.61	44.35	7.99	42.24
6.48	52.08	6.86	49.20	7.24	46.62	7.62	44.29	8.00	42.19
6.49	52.00	6.87	49.13	7.25	46.55	7.63	44.23	8.01	42.13
6.50	51.92	6.88	49.06	7.26	46.49	7.64	44.18	8.02	42.08
6.51	51.84	6.89	48.98	7.27	46.42	7.65	44.12	8.03	42.03
6.52	51.76	6.90	48.91	7.28	46.36	7.66	44.06	8.04	41.98
6.53	51.68	6.91	48.84	7.29	46.30	7.67	44.00	8.05	41.93
6.54	51.61	6.92	48.77	7.30	46.23	7.68	43.95	8.06	41.87
6.55	51.53	6.93	48.70	7.31	46.17	7.69	43.89	8.07	41.82
6.56	51.45	6.94	48.63	7.32	46.11	7.70	43.83	8.08	41.77
6.57	51.37	6.95	48.56	7.33	46.04	7.71	43.77	8.09	41.72

Continued

Conversion between Corneal Front Surface Radius of Curvature (r; mm) and Corneal Power (K; D)* (Continued)

r (mm)	K (D)	r (mm)	K (D)	r (mm)	K (D)	r (mm)	K (D)	r (mm)	K (D)
8.10	41.67	8.42	40.08	8.74	38.62	9.06	37.25	9.38	35.98
8.11	41.62	8.43	40.04	8.75	38.57	9.07	37.21	9.39	35.94
8.12	41.56	8.44	39.99	8.76	38.53	9.08	37.17	9.40	35.90
8.13	41.51	8.45	39.94	8.77	38.48	9.09	37.13	9.41	35.87
8.14	41.46	8.46	39.89	8.78	38.44	9.10	37.09	9.42	35.83
8.15	41.41	8.47	39.85	8.79	38.40	9.11	37.05	9.43	35.79
8.16	41.36	8.48	39.80	8.80	38.35	9.12	37.01	9.44	35.75
8.17	41.31	8.49	39.75	8.81	38.31	9.13	36.97	9.45	35.71
8.18	41.26	8.50	39.71	8.82	38.27	9.14	36.93	9.46	35.68
8.19	41.21	8.51	39.66	8.83	38.22	9.15	36.89	9.47	35.64
8.20	41.16	8.52	39.61	8.84	38.18	9.16	36.84	9.48	35.60
8.21	41.11	8.53	39.57	8.85	38.14	9.17	36.80	9.49	35.56
8.22	41.06	8.54	39.52	8.86	38.09	9.18	36.76	9.50	35.53
8.23	41.01	8.55	39.47	8.87	38.05	9.19	36.72	9.51	35.49
8.24	40.96	8.56	39.43	8.88	38.01	9.20	36.68	9.52	35.45
8.25	40.91	8.57	39.38	8.89	37.96	9.21	36.64	9.53	35.41
8.26	40.86	8.58	39.34	8.90	37.92	9.22	36.61	9.54	35.38
8.27	40.81	8.59	39.29	8.91	37.88	9.23	36.57	9.55	35.34
8.28	40.76	8.60	39.24	8.92	37.84	9.24	36.53	9.56	35.30
8.29	40.71	8.61	39.20	8.93	37.79	9.25	36.49	9.57	35.27
8.30	40.66	8.62	39.15	8.94	37.75	9.26	36.45	9.58	35.23
8.31	40.61	8.63	39.11	8.95	37.71	9.27	36.41	9.59	35.19
8.32	40.56	8.64	39.06	8.96	37.67	9.28	36.37	9.60	35.16
8.33	40.52	8.65	39.02	8.97	37.63	9.29	36.33	9.61	35.12
8.34	40.47	8.66	38.97	8.98	37.58	9.30	36.29	9.62	35.08
8.35	40.42	8.67	38.93	8.99	37.54	9.31	36.25	9.63	35.05
8.36	40.37	8.68	38.88	9.00	37.50	9.32	36.21	9.64	35.01
8.37	40.32	8.69	38.84	9.01	37.46	9.33	36.17	9.65	34.97
8.38	40.27	8.70	38.79	9.02	37.42	9.34	36.13	9.66	34.94
8.39	40.23	8.71	38.75	9.03	37.38	9.35	36.10	9.67	34.90
8.40	40.18	8.72	38.70	9.04	37.33	9.36	36.06	9.68	34.87
8.41	40.13	8.73	38.66	9.05	37.29	9.37	36.02	9.69	34.83

*Based on the equation: Surface power (D) = $(1.3375 - 1.0)$/ radius (m)
(Courtesy of Adrian S Bruce and Suzanne E Efron.)

APPENDIX
E

Extended Keratometer Range Conversion

Conversion of Keratometer Reading (D) to its Extended Value (D) when a +1.25 D Lens (for Steep Corneas) or a −1.00 D Lens (for Flat Corneas) is Held in Front of the Keratometer

STEEP CORNEAS (USING A +1.25 D LENS)*

Keratometer Reading (D)	Extended Value (D)	Keratometer Reading (D)	Extended Value (D)	Keratometer Reading (D)	Extended Value (D)
43.00	50.13	46.13	53.78	49.25	57.42
43.13	50.28	46.25	53.92	49.38	57.57
43.25	50.42	46.38	54.07	49.50	57.71
43.38	50.57	46.50	54.21	49.63	57.86
43.50	50.72	46.63	54.36	49.75	58.00
43.63	50.86	46.75	54.51	49.88	58.15
43.75	51.01	46.88	54.65	50.00	58.30
43.88	51.15	47.00	54.80	50.13	58.44
44.00	51.30	47.13	54.94	50.25	58.59
44.13	51.44	47.25	55.09	50.38	58.73
44.25	51.59	47.38	55.23	50.50	58.88
44.38	51.74	47.50	55.38	50.63	59.02
44.50	51.88	47.63	55.53	50.75	59.17
44.63	52.03	47.75	55.67	50.88	59.32
44.75	52.17	47.88	55.82	51.00	59.46
44.88	52.32	48.00	55.96	51.13	59.61
45.00	52.47	48.13	56.11	51.25	59.75
45.13	52.61	48.25	56.25	51.38	59.90
45.25	52.76	48.38	56.40	51.50	60.04
45.38	52.90	48.50	56.55	51.63	60.19
45.50	53.05	48.63	56.69	51.75	60.34
45.63	53.19	48.75	56.84	51.88	60.48
45.75	53.34	48.88	56.98	52.00	60.63
45.88	53.49	49.00	57.13		
46.00	53.63	49.13	57.27		

FLAT CORNEAS (USING A −1.00 D LENS)†

Keratometer Reading (D)	Extended Value (D)	Keratometer Reading (D)	Extended Value (D)	Keratometer Reading (D)	Extended Value (D)
36.00	30.87	38.12	32.70	40.25	34.52
36.12	30.98	38.25	32.80	40.37	34.63
36.25	31.09	38.37	32.91	40.50	34.73
36.37	31.19	38.50	33.02	40.62	34.84
36.50	31.30	38.62	33.12	40.75	34.95
36.62	31.41	38.75	33.23	40.87	35.06
36.75	31.52	38.87	33.34	41.00	35.16
36.87	31.62	39.00	33.45	41.12	35.27
37.00	31.73	39.12	33.55	41.25	35.38
37.12	31.84	39.25	33.66	41.37	35.48
37.25	31.94	39.37	33.77	41.50	35.59
37.37	32.05	39.50	33.88	41.62	35.70
37.50	32.16	39.62	33.98	41.75	35.81
37.62	32.27	39.75	34.09	41.87	35.91
37.75	32.37	39.87	34.20	42.00	36.02
37.87	32.48	40.00	34.30		
38.00	32.59	40.12	34.41		

*Based on the equation: Extended = (1.166 × keratometer) − 0.005.

†Based on the equation: Extended = (1.858 × keratometer) − 0.014.

(Derived from data in: Mandell, R. B., (1988) Dioptral and mm curves for extended keratometer range. Appendix 7. In Contact Lens Practice (4th ed. pp. 998–999). Springfeld, IL: Charles C. Thomas.)

(Courtesy of Adrian S Bruce.)

APPENDIX

F

Soft Lens Average Thickness

The Average Thickness (mm) of Soft Lenses of Given Centre Thickness (mm) and Lens Power (D)

Centre Thickness (mm)	AVERAGE THICKNESS (mm) FOR VARIOUS LENS POWERS (D)											
	+8.00	+6.00	+4.00	+2.00	−2.00	−4.00	−6.00	−8.00	−10.00	−12.00	−14.00	−16.00
0.03					0.047	0.062	0.075	0.088	0.099	0.110	0.121	0.131
0.04					0.057	0.073	0.087	0.100	0.113	0.124	0.136	0.147
0.05					0.067	0.084	0.098	0.112	0.125	0.137	0.149	0.160
0.06					0.077	0.094	0.109	0.124	0.137	0.150	0.162	0.174
0.07					0.087	0.104	0.120	0.135	0.148	0.162	0.174	0.186
0.08				0.052	0.097	0.114	0.130	0.145	0.160	0.173	0.186	0.199
0.09				0.062	0.107	0.124	0.141	0.156	0.171	0.184	0.198	0.210
0.10				0.072	0.116	0.134	0.151	0.167	0.181	0.195	0.209	0.222
0.11				0.082	0.126	0.144	0.161	0.177	0.192	0.206	0.220	0.233
0.12				0.091	0.136	0.154	0.171	0.187	0.203	0.217	0.231	0.245
0.13			0.071	0.101	0.145	0.164	0.181	0.198	0.213	0.228	0.242	0.256
0.14			0.082	0.111	0.155	0.174	0.191	0.208	0.223	0.238	0.253	0.267
0.15			0.093	0.121	0.165	0.184	0.201	0.218	0.234	0.249	0.263	0.278
0.16			0.103	0.131	0.174	0.193	0.211	0.228	0.244	0.259	0.274	0.288
0.17		0.078	0.113	0.140	0.184	0.203	0.221	0.238	0.254	0.269	0.284	0.299
0.18		0.090	0.123	0.150	0.194	0.213	0.231	0.248	0.264	0.280	0.295	0.309
0.19		0.101	0.134	0.160	0.203	0.223	0.241	0.258	0.274	0.290	0.305	0.320
0.20		0.112	0.144	0.169	0.213	0.232	0.250	0.268	0.284	0.300	0.315	0.330
0.21		0.123	0.153	0.179	0.223	0.242	0.260	0.278	0.294	0.310	0.326	0.341
0.22	0.094	0.134	0.163	0.189	0.232	0.252	0.270	0.287	0.304	0.320	0.336	0.351
0.23	0.107	0.144	0.173	0.198	0.242	0.261	0.280	0.297	0.314	0.330	0.346	0.361
0.24	0.119	0.155	0.183	0.208	0.251	0.271	0.290	0.307	0.324	0.340	0.356	0.372
0.25	0.131	0.165	0.193	0.218	0.261	0.281	0.299	0.317	0.334	0.350	0.366	0.382

*Based on the following assumptions:

- back optic zone radius = 8.7 mm
- optic zone diameter = 8.00 mm
- refractive index (n) = 1.48 − 0.0015 × water content
- water content = 55%
  (Note: variations to 38% and 74% only affect average thickness by ± 0.03 mm)
- minimum thickness at edge of optic zone for plus lenses = 0.03 mm

(Based on the theory outlined in: Brennan, N. A. (1984). Average thickness of a hydrogel lens for gas transmissibility calculations. Am. J. Optom. Physiol. Opt., 61, 627–635.)

(Courtesy of Adrian S Bruce.)

APPENDIX

G

Soft Lens Oxygen Performance

Conversion Between Soft (hydrogel) Lens Water Content (%), Barrer (Fatt units) and ISO Oxygen Permeability (Dk) Values, and Fatt Oxygen Transmissibility (Dk/t) Values for Various Lens Thicknesses

Water Content (%)	Dk Barrer Units* at 35°C	Dk ISO Units† at 35°C	Dk/t‡ AT 35°C (BASED ON BARRER UNITS) FOR VARIOUS LENS THICKNESSES (t, mm)												
			0.03	0.04	0.05	0.06	0.07	0.08	0.09	0.10	0.12	0.15	0.20	0.25	0.30
35	6.7	5.0	22.3	16.8	13.4	11.2	9.6	8.4	7.4	6.7	5.6	4.5	3.4	2.7	2.2
36	7.0	5.2	23.2	17.4	13.9	11.6	10.0	8.7	7.7	7.0	5.8	4.6	3.5	2.8	2.3
37	7.3	5.4	24.2	18.1	14.5	12.1	10.4	9.1	8.1	7.3	6.0	4.8	3.6	2.9	2.4
38	7.5	5.7	25.2	18.9	15.1	12.6	10.8	9.4	8.4	7.5	6.3	5.0	3.8	3.0	2.5
39	7.9	5.9		19.6	15.7	13.1	11.2	9.8	8.7	7.9	6.5	5.2	3.9	3.1	2.6
40	8.2	6.1		20.4	16.3	13.6	11.7	10.2	9.1	8.2	6.8	5.4	4.1	3.3	2.7
41	8.5	6.4		21.3	17.0	14.2	12.1	10.6	9.4	8.5	7.1	5.7	4.3	3.4	2.8
42	8.8	6.6		22.1	17.7	14.7	12.6	11.1	9.8	8.8	7.4	5.9	4.4	3.5	2.9
43	9.2	6.9		23.0	18.4	15.3	13.2	11.5	10.2	9.2	7.7	6.1	4.6	3.7	3.1
44	9.6	7.2		23.9	19.2	16.0	13.7	12.0	10.6	9.6	8.0	6.4	4.8	3.8	3.2
45	10.0	7.5		24.9	19.9	16.6	14.2	12.5	11.1	10.0	8.3	6.6	5.0	4.0	3.3
46	10.4	7.8			20.7	17.3	14.8	13.0	11.5	10.4	8.6	6.9	5.2	4.1	3.5
47	10.8	8.1			21.6	18.0	15.4	13.5	12.0	10.8	9.0	7.2	5.4	4.3	3.6
48	11.2	8.4			22.5	18.7	16.0	14.0	12.5	11.2	9.4	7.5	5.6	4.5	3.7
49	11.7	8.8			23.4	19.5	16.7	14.6	13.0	11.7	9.7	7.8	5.8	4.7	3.9
50	12.2	9.1			24.3	20.3	17.4	15.2	13.5	12.2	10.1	8.1	6.1	4.9	4.1
51	12.6	9.5				21.1	18.1	15.8	14.1	12.6	10.5	8.4	6.3	5.1	4.2
52	13.2	9.9				21.9	18.8	16.5	14.6	13.2	11.0	8.8	6.6	5.3	4.4
53	13.7	10.3				22.8	19.6	17.1	15.2	13.7	11.4	9.1	6.8	5.5	4.6
54	14.2	10.7				23.7	20.4	17.8	15.8	14.2	11.9	9.5	7.1	5.7	4.7
55	14.8	11.1				24.7	21.2	18.5	16.5	14.8	12.4	9.9	7.4	5.9	4.9
56	15.4	11.6					22.0	19.3	17.1	15.4	12.9	10.3	7.7	6.2	5.1
57	16.1	12.0					22.9	20.1	17.8	16.1	13.4	10.7	8.0	6.4	5.4
58	16.7	12.5					23.9	20.9	18.6	16.7	13.9	11.1	8.4	6.7	5.6
59	17.4	13.0					24.8	21.7	19.3	17.4	14.5	11.6	8.7	7.0	5.8
60	18.1	13.6					25.8	22.6	20.1	18.1	15.1	12.1	9.0	7.2	6.0
61	18.8	14.1						23.5	20.9	18.8	15.7	12.5	9.4	7.5	6.3
62	19.6	14.7						24.5	21.7	19.6	16.3	13.0	9.8	7.8	6.5
63	20.4	15.3							22.6	20.4	17.0	13.6	10.2	8.1	6.8
64	21.2	15.9							23.5	21.2	17.7	14.1	10.6	8.5	7.1
65	22.1	16.5							24.5	22.1	18.4	14.7	11.0	8.8	7.4
66	22.9	17.2								22.9	19.1	15.3	11.5	9.2	7.6
67	23.9	17.9								23.9	19.9	15.9	11.9	9.5	8.0
68	24.8	18.6								24.8	20.7	16.6	12.4	9.9	8.3
69	25.8	19.4								25.8	21.5	17.2	12.9	10.3	8.6
70	26.9	20.2								26.9	22.4	17.9	13.4	10.8	9.0
71	28.0	21.0									23.3	18.7	14.0	11.2	9.3

Continued

Conversion Between Soft (hydrogel) Lens Water Content (%), Barrer (Fatt units) and ISO Oxygen Permeability (Dk) Values, and Fatt Oxygen Transmissibility (Dk/t) Values for Various Lens Thicknesses (Continued)

Water Content (%)	Dk Barrer Units* at 35°C	Dk ISO Units† at 35°C	Dk/t‡ AT 35°C (BASED ON BARRER UNITS) FOR VARIOUS LENS THICKNESSES (t, mm)												
			0.03	0.04	0.05	0.06	0.07	0.08	0.09	0.10	0.12	0.15	0.20	0.25	0.30
72	29.1	21.8									24.3	19.4	14.6	11.6	9.7
73	30.3	22.7									25.2	20.2	15.1	12.1	10.1
74	31.5	23.6										21.0	15.8	12.6	10.5
75	32.8	24.6										21.9	16.4	13.1	10.9
76	34.1	25.6										22.7	17.1	13.6	11.4
77	35.5	26.6										23.7	17.8	14.2	11.8
78	36.9	27.7										24.6	18.5	14.8	12.3
79	38.4	28.8											19.2	15.4	12.8
80	40.0	30.0											20.0	16.0	13.3

- For lenses ≤±1.50 D: average thickness = centre thickness.
- Dk/t values for thicknesses below a minimum manufacturable thickness are not shown.
- Data in this table are based on the Morgan–Efron equation, which corrects for boundary and edge effect errors during polarographic measurement: $Dk = 1.67 \times 10^{-11} \exp^{0.0397WC}$ (Morgan, P. B. & Efron, N. (1998). The oxygen performance of contemporary hydrogel contact lenses. Contact Lens Ant. Eye, 21, 3–6.)
- The shaded cells represent Dk/t values that are considered to be adequate for open-eye (daily) lens wear; that is, $Dk/t < 12$ Barrer/cm (Benjamin W. J. (1996). Downsizing of Dk and Dk/L: The difficulty in using hPa instead of mmHg. Int. Contact Lens Clin., 23, 188–189.)
- The data in this table do not apply to silicone hydrogel lenses, which are described by a water content–Dk relationship that is essentially the inverse of that which is used here to describe hydrogel lenses.

*Traditional units of oxygen permeability are: $\times 10^{-11}$ $(cm^2 \times ml\ O_2) / (s \times ml \times mmHg)$, or Barrer.

†ISO units of oxygen permeability are: $\times 10^{-11}$ $(cm^2 \times ml\ O_2) / (s \times ml \times hPa)$.

‡Traditional units of oxygen transmissibility are: $\times 10^{-9}$ $(cm \times ml\ O_2) / (s \times ml \times mmHg)$, or Barrer/cm.

(Courtesy of Adrian S Bruce.)

APPENDIX

H

Constant Edge Clearance Rigid Lens Designs

Theoretical Edge Clearances for a Lens Fitted with 10 μm Central Clearance on a Cornea with a Shape Factor of 0.85*

8.40 m DIAMETER – 69 μm EDGE CLEARANCE																
BOZR	7.00	7.10	7.20	7.30	7.40	7.50	7.60	7.70	7.80	7.90	8.00	8.10	8.20	8.30	8.40	8.50
BOZD	7.40	7.40	7.40	7.40	7.40	7.40	7.40	7.40	7.40	7.40	7.40	7.40	7.40	7.40	7.40	7.40
BPR1	7.80	7.90	8.05	8.20	8.30	8.45	8.60	8.75	8.90	9.00	9.15	9.25	9.40	9.50	9.65	9.80
BPZD1	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00
BPR2	9.80	10.10	10.30	10.50	10.90	11.20	11.40	11.70	12.00	12.40	12.60	13.10	13.40	13.80	14.10	14.40
TD	8.40	8.40	8.40	8.40	8.40	8.40	8.40	8.40	8.40	8.40	8.40	8.40	8.40	8.40	8.40	8.40
8.80 m DIAMETER – 73 μm EDGE CLEARANCE																
BOZR	7.00	7.10	7.20	7.30	7.40	7.50	7.60	7.70	7.80	7.90	8.00	8.10	8.20	8.30	8.40	8.50
BOZD	7.60	7.60	7.60	7.60	7.60	7.60	7.60	7.60	7.60	7.60	7.60	7.60	7.60	7.60	7.60	7.60
BPR1	7.70	7.85	7.95	8.10	8.20	8.35	8.45	8.60	8.75	8.90	9.00	9.15	9.25	9.40	8.55	9.65
BPZD1	8.30	8.30	8.30	8.30	8.30	8.30	8.30	8.30	8.30	8.30	8.30	8.30	8.30	8.30	8.30	8.30
BPR2	8.90	9.10	9.30	9.50	9.80	10.00	10.30	10.40	10.70	10.80	11.10	11.40	11.70	11.90	12.10	12.50
TD	8.80	8.80	8.80	8.80	8.80	8.80	8.80	8.80	8.80	8.80	8.80	8.80	8.80	8.80	8.80	8.80
9.20 m DIAMETER – 80 μm EDGE CLEARANCE																
BOZR	7.00	7.10	7.20	7.30	7.40	7.50	7.60	7.70	7.80	7.90	8.00	8.10	8.20	8.30	8.40	8.50
BOZD	7.80	7.80	7.80	7.80	7.80	7.80	7.80	7.80	7.80	7.80	7.80	7.80	7.80	7.80	7.80	7.80
BPR1	7.60	7.70	7.85	7.95	8.10	8.20	8.35	8.45	8.60	8.70	8.85	8.95	9.10	9.20	9.35	9.47
BPZD1	8.60	8.60	8.60	8.60	8.60	8.60	8.60	8.60	8.60	8.60	8.60	8.60	8.60	8.60	8.60	8.60
BPR2	8.60	8.80	9.00	9.20	9.40	9.60	9.80	10.00	10.20	10.40	10.60	10.90	11.10	11.30	11.60	11.83
TD	9.20	9.20	9.20	9.20	9.20	9.20	9.20	9.20	9.20	9.20	9.20	9.20	9.20	9.20	9.20	9.20
9.60 m DIAMETER – 90 μm EDGE CLEARANCE																
BOZR	7.00	7.10	7.20	7.30	7.40	7.50	7.60	7.70	7.80	7.90	8.00	8.10	8.20	8.30	8.40	8.50
BOZD	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00
BPR1	7.60	7.70	7.80	7.95	8.10	8.20	8.30	8.45	8.55	8.70	8.85	8.95	9.10	9.20	9.35	9.50
BPZD1	8.90	8.90	8.90	8.90	8.90	8.90	8.90	8.90	8.90	8.90	8.90	8.90	8.90	8.90	8.90	8.90
BPR2	8.30	8.50	8.70	8.90	9.00	9.30	9.50	9.70	9.90	10.10	10.20	10.50	10.60	10.90	11.00	11.20
TD	9.60	9.60	9.60	9.60	9.60	9.60	9.60	9.60	9.60	9.60	9.60	9.60	9.60	9.60	9.60	9.60
10.00 mm DIAMETER – 105 μm EDGE CLEARANCE																
BOZR	7.00	7.10	7.20	7.30	7.40	7.50	7.60	7.70	7.80	7.90	8.00	8.10	8.20	8.30	8.40	8.50
BOZD	8.20	8.20	8.20	8.20	8.20	8.20	8.20	8.20	8.20	8.20	8.20	8.20	8.20	8.20	8.20	8.20
BPR1	7.65	7.70	7.80	7.95	8.10	8.20	8.35	8.45	8.65	8.70	8.85	9.00	9.15	9.25	9.40	9.50
BPZD1	8.90	8.90	8.90	8.90	8.90	8.90	8.90	8.90	8.90	8.90	8.90	8.90	8.90	8.90	8.90	8.90
BPR2	8.00	8.15	8.35	8.50	8.60	8.80	8.90	9.10	9.15	9.45	9.60	9.75	9.90	10.10	10.25	10.45
BPZD2	9.50	9.50	9.50	9.50	9.50	9.50	9.50	9.50	9.50	9.50	9.50	9.50	9.50	9.50	9.50	9.50
BPR3	8.10	8.30	8.40	8.60	8.80	9.00	9.20	9.30	9.50	9.70	9.80	10.00	10.20	10.40	10.50	10.70
TD	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00

*(Based on the design concept of Guillon, M., Lydon, D. P. M. & Sammons, W. A. (1983). Designing rigid gas-permeable contact lenses using the edge clearance technique. J. Br. Contact Lens Assoc., 6, 19–25.)

(Courtesy of Graeme Young.)

APPENDIX

I

Soft Toric Lens Misalignment Demonstrator

Residual Refractive Error Induced by Mislocation of Toric Lenses of Given Cylindrical Powers, Based upon an Ocular Refraction of Plano/−cyl × 180

Example

- Ocular refraction (required refractive correction) is: plano/−1.00 × 180
- A lens is placed on the eye of back vertex power: plano/−1.00 × 180
- An overrefracton yields a residual error of: +0.34/−0.68 × 35
- From the table, a mislocation is indicated of: −20°
- The lens back vertex power in situ is: plano/−1.00 × 160

Mislocation (−)(°)	−1.00 D Cylinder	−2.00 D Cylinder	−3.00 D Cylinder
5	0.09/−0.17 × 42.5	0.17/−0.35 × 42.5	0.26/−0.52 × 42.5
10	0.17/−0.35 × 40.0	0.35/−0.69 × 40.0	0.52/−1.04 × 40.0
15	0.26/−0.52 × 37.5	0.52/−1.04 × 37.5	0.78/−1.55 × 37.5
20	0.34/−0.68 × 35.0	0.68/−1.37 × 35.0	1.03/−2.05 × 35.0
25	0.42/−0.85 × 32.5	0.85/−1.69 × 32.5	1.27/−2.54 × 32.5
30	0.50/−1.00 × 30.0	1.00/−2.00 × 30.0	1.50/−3.00 × 30.0
35	0.57/−1.15 × 27.5	1.15/−2.29 × 27.5	1.72/−3.44 × 27.5
40	0.64/−1.29 × 25.0	1.29/−2.57 × 25.0	1.93/−3.86 × 25.0
45	0.71/−1.41 × 22.5	1.41/−2.83 × 22.5	2.12/−4.24 × 22.5
50	0.77/−1.53 × 20.0	1.53/−3.06 × 20.0	2.30/−4.60 × 20.0
55	0.82/−1.64 × 17.5	1.64/−3.28 × 17.5	2.46/−4.91 × 17.5
60	0.87/−1.73 × 15.0	1.73/−3.46 × 15.0	2.60/−5.20 × 15.0
65	0.91/−1.81 × 12.5	1.81/−3.63 × 12.5	2.72/−5.44 × 12.5
70	0.94/−1.88 × 10.0	1.88/−3.76 × 10.0	2.82/−5.64 × 10.0
75	0.97/−1.93 × 7.5	1.93/−3.86 × 7.5	2.90/−5.80 × 7.5
80	0.98/−1.97 × 5.0	1.97/−3.94 × 5.0	2.95/−5.91 × 5.0
85	1.00/−1.99 × 2.5	1.99/−3.98 × 2.5	2.99/−5.98 × 2.5
90	1.00/−2.00 × 0.0	2.00/−4.00 × 0.0	3.00/−6.00 × 0.0

Rules of thumb for soft toric mislocation:

1. The spherical equivalent is zero if the error is purely due to axis misalignment.
2. The direction of lens misalignment is always opposite to the axis of the overrefraction, relative to the prescribed cylinder axis.
3. LARS: 'left add, right subtract'. When allowing for nasal rotation in the right eye, the amount of rotation should be subtracted from the required cylinder axis and vice versa for the left eye.

(Generated using the formulae in: Lindsay, R. G., Bruce, A. S., Brennan, N. A. & Pianta, M. J. (1997). Determining axis misalignment and power errors of toric soft lenses. Int. Contact Lens. Clin., 24, 101–107.)

(Courtesy of Adrian S Bruce.)

APPENDIX
J

Dry-eye Questionnaire

A Typical Dry-eye Questionnaire

Symptom	Frequency			
	Never	Sometimes	Often	Constantly
Sandy or gritty feeling				
Burning				
Dryness				
Soreness				
Scratchiness				
Itching				
Eye discomfort on waking				
Tearing (watery eyes)				
Foreign-body sensation				
Eye pain				
Redness				
Mucus discharge				
Light sensitivity				
Blurred vision				
Infection of lids or eye				
Hayfever				
Other allergy				
Nasal congestion				
Cough				
Bronchitis				
Cold symptoms				
Sinus congestion				
Dryness of throat/mouth/vagina				
Trouble swallowing food				
Asthma symptoms				
Joint pain				
Muscle pain				

DO YOUR EYES SEEM OVERLY SENSITIVE TO:

Cigarette smoke	■	Swimming	■	Smog	■	Alcohol	■
Air conditioning	■	Sunshine	■	Heater and air blowers	■	Wind	■
Dust	■	Use of VDUs	■	Pollen	■	Eye drops	■

GENERAL QUESTIONS RELATING TO DRY EYE	Yes	No
Do you wear contact lenses?		
Have you previously tried to wear contact lenses?		
Do you use artificial tears or drops?		
Have you ever been told you sleep with your eyes open?		
Have you ever been treated for dry eyes?		
Do you take antihistamines?		
Do you take birth control pills?		
Are you taking diuretics (water pills)?		
Are you taking any other medication (prescribed or over the counter)? If yes, give brand and reason for taking medication		

Condition	Have You or Any Blood Relative Had Any of the Following?		
	Yourself	Relative	Relationship
Arthritis			
Thyroid disease			
Lupus			
Sarcoidosis			
Asthma			
Sjögren's syndrome			
Skin disorders			
Heart disease			
Hypertension			
Gout			
Cataract			
Diabetes			
Glaucoma			

(Adapted with permission from: Lowther, G. E. (1997). Examination of patients and predicting tear-film related problems with hydrogel lens wear. In Dryness, Tears and Contact Lens Wear (pp. 23–53). Oxford: Butterworth-Heinemann)

(Courtesy of Keith H Edwards.)

APPENDIX

K

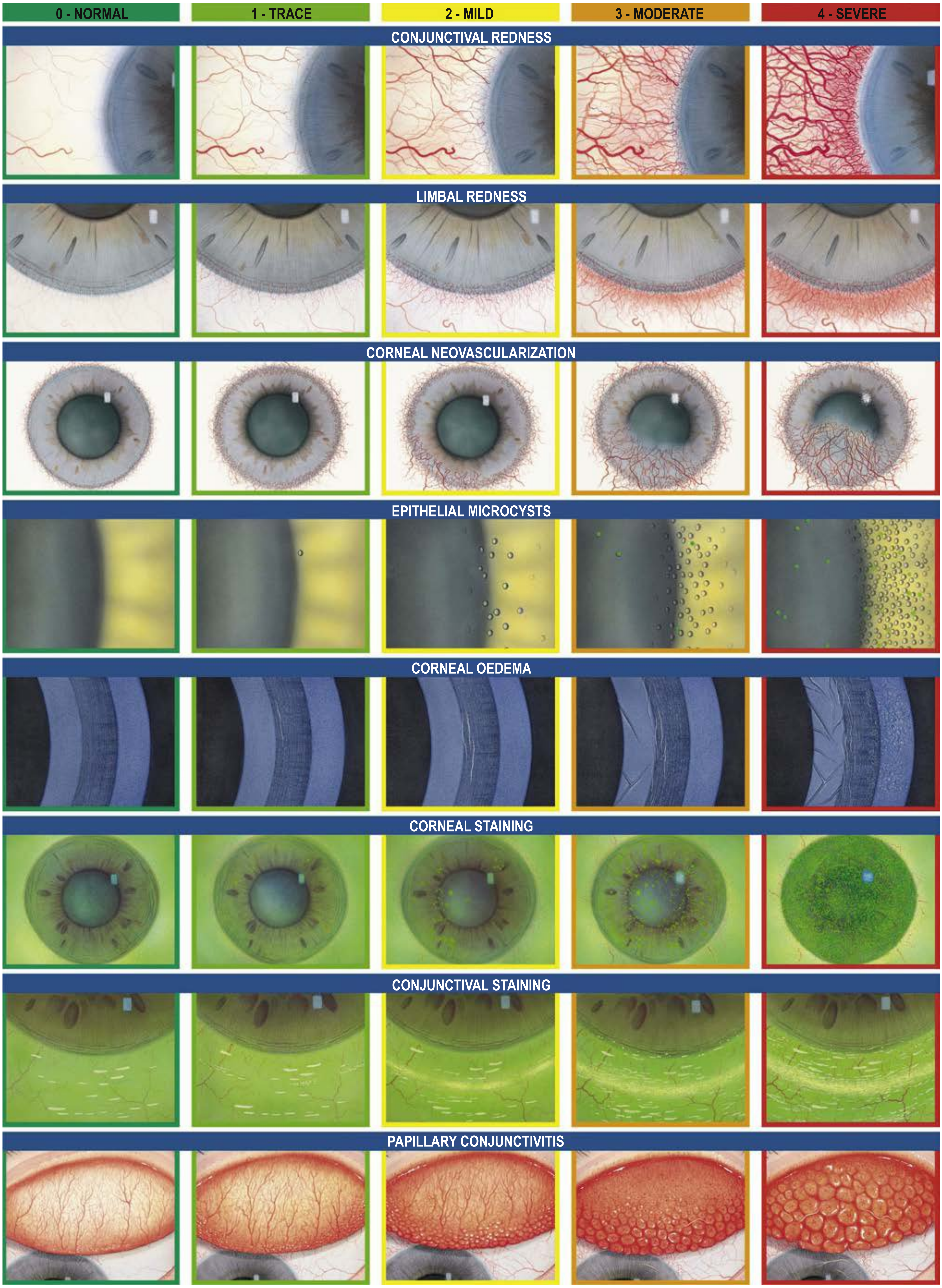
Efron Grading Scales for Contact Lens Complications

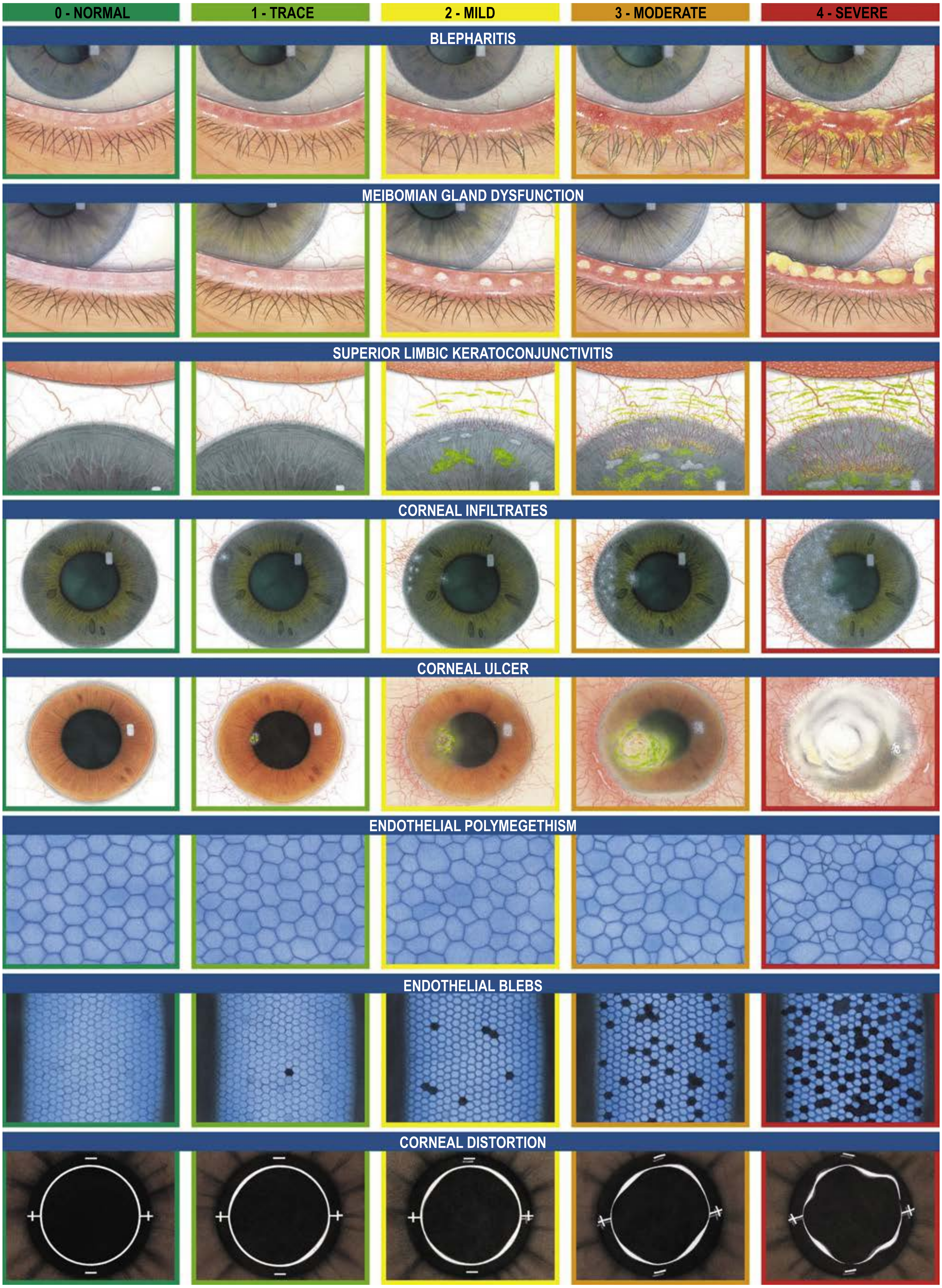
The grading scales presented on the following two pages were devised by Professor Nathan Efron and painted by the ophthalmic artist, Terry R Tarrant.

These grading scales are designed to assist practitioners to quantify the level of severity of a variety of contact lens complications. The eight complications on the first page are those that are more likely to be encountered in contact lens practice. Many of these complications are graded routinely by some practitioners. The complications on the second page are less commonly encountered in contact lens practice, and represent pathology that is rare or unusual.

An explanation as to how to use these grading scales is given in Chapter 39.

The development of these grading scales was kindly sponsored by CooperVision.


0 - NORMAL
1 - TRACE
2 - MILD
3 - MODERATE
4 - SEVERE
CONJUNCTIVAL REDNESS
LIMBAL REDNESS
CORNEAL NEOVASCULARIZATION
EPITHELIAL MICROCYSTS
CORNEAL OEDEMA
CORNEAL STAINING
CONJUNCTIVAL STAINING
PAPILLARY CONJUNCTIVITIS

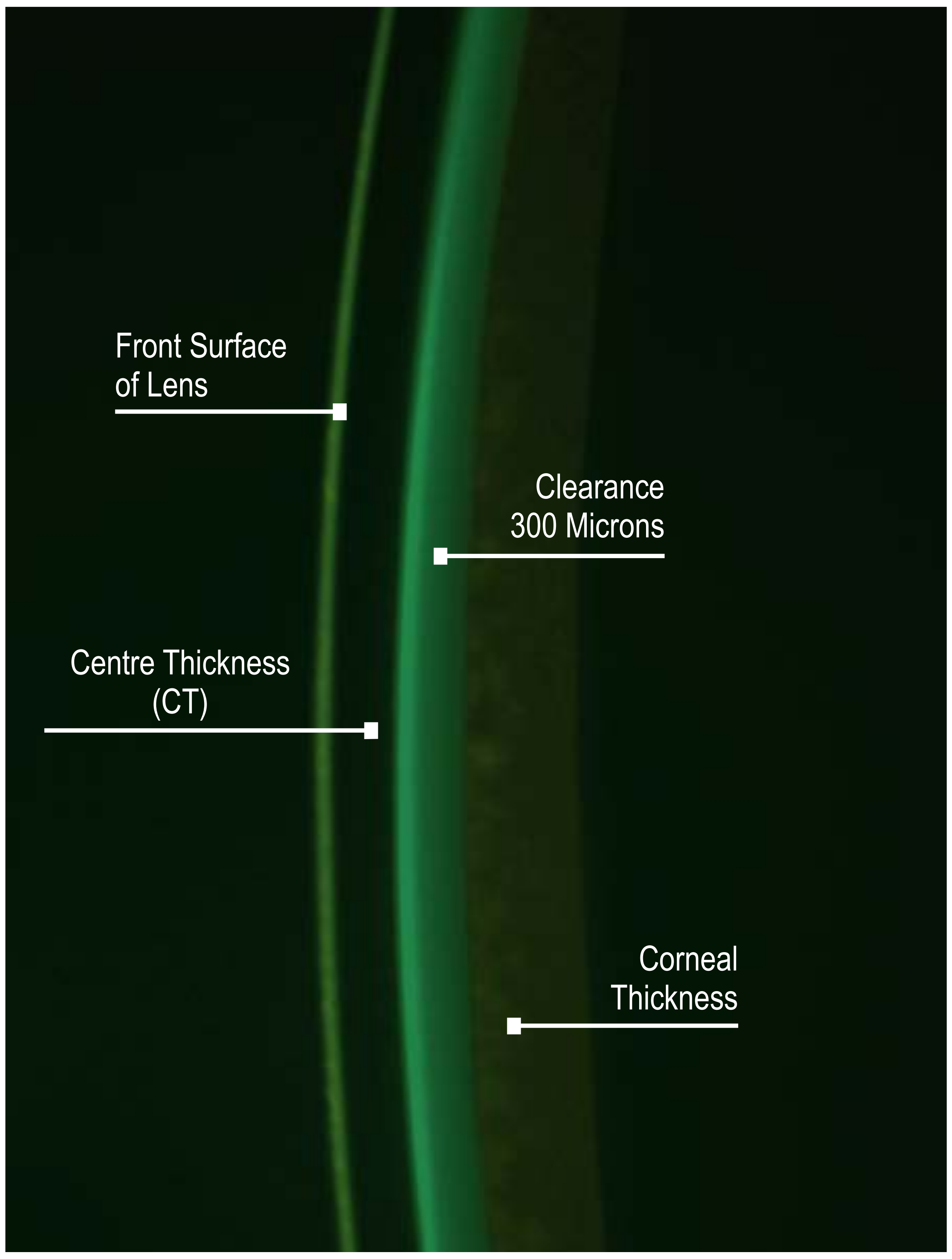

0 - NORMAL
1 - TRACE
2 - MILD
3 - MODERATE
4 - SEVERE
BLEPHARITIS
MEIBOMIAN GLAND DYSFUNCTION
SUPERIOR LIMBIC KERATOCONJUNCTIVITIS
CORNEAL INFILTRATES
CORNEAL ULCER
ENDOTHELIAL POLYMEGETHISM
ENDOTHELIAL BLEBS
CORNEAL DISTORTION

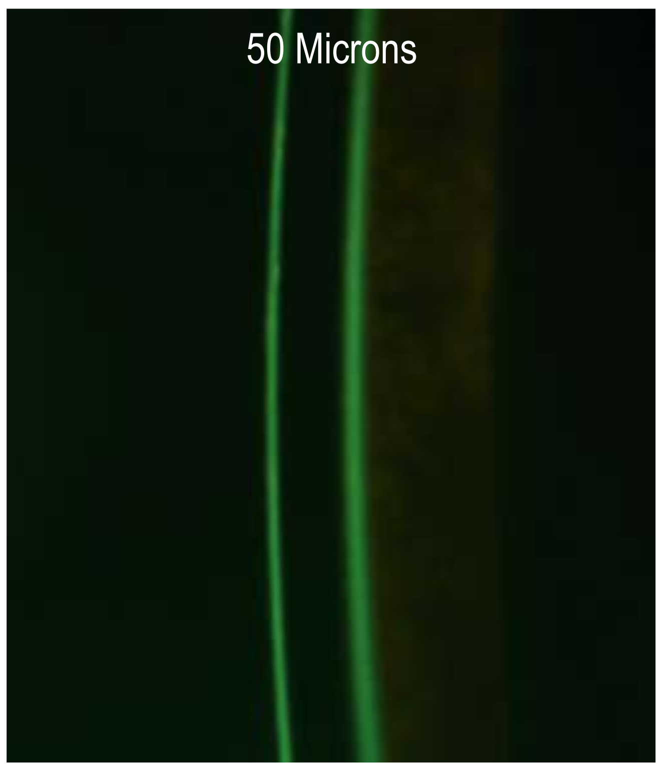
APPENDIX

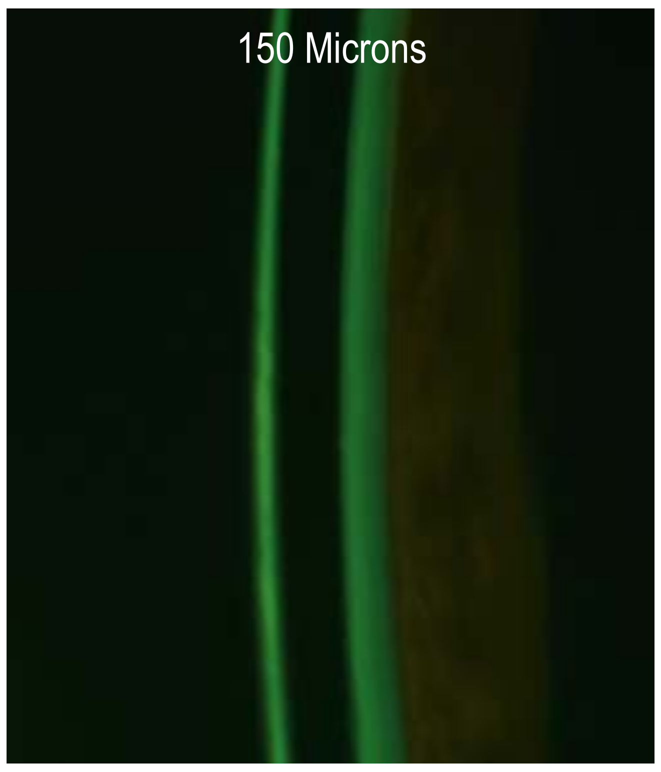
L

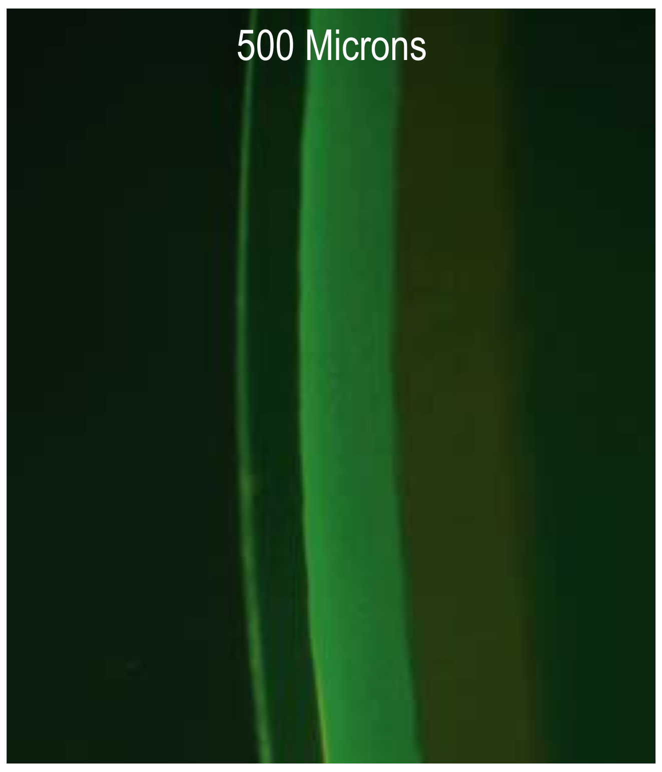
Scleral Lens Fit Scales

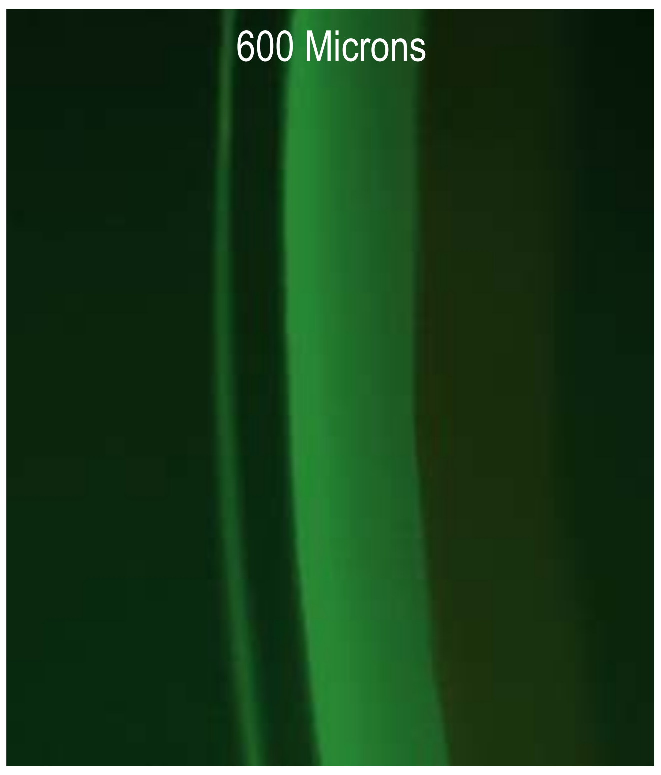
To accurately estimate the amount of vaulting (clearance) underneath the posterior surface of a scleral lens necessitates a reference point for comparison. Although some have suggested corneal thickness for the reference, we prefer the centre thickness (CT) of the lens itself, which is specified by the manufacturer. In each of the examples below, the CT is 0.30 mm (300 µm). In most scleral lens designs, the ideal amount of clearance is about 300 µm.


Front Surface of Lens
Clearance 300 Microns
Centre Thickness (CT)
Corneal Thickness

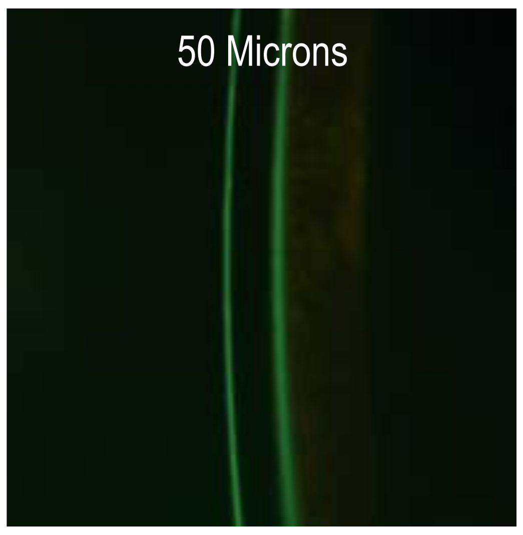


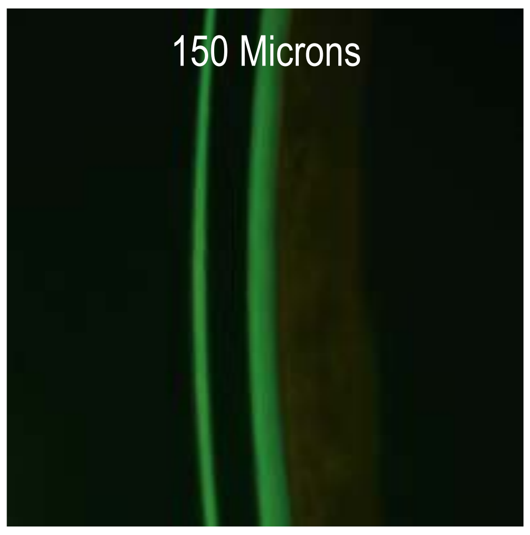

150 Microns

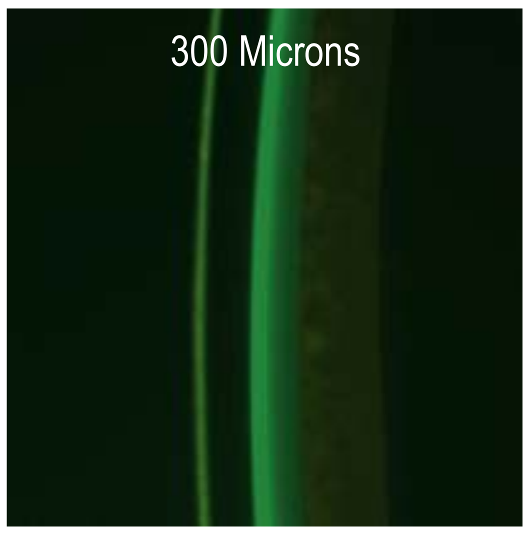

500 Microns

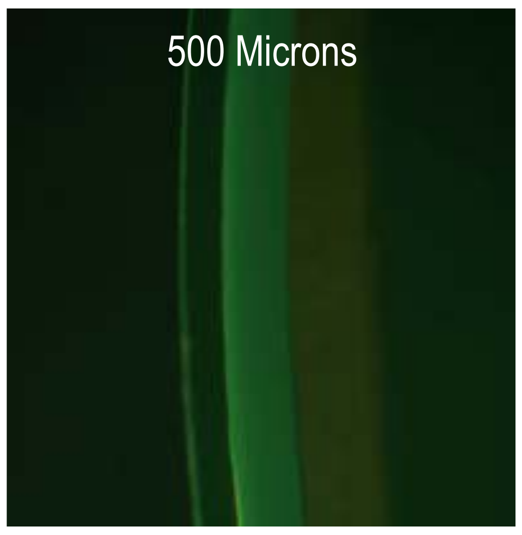

600 Microns

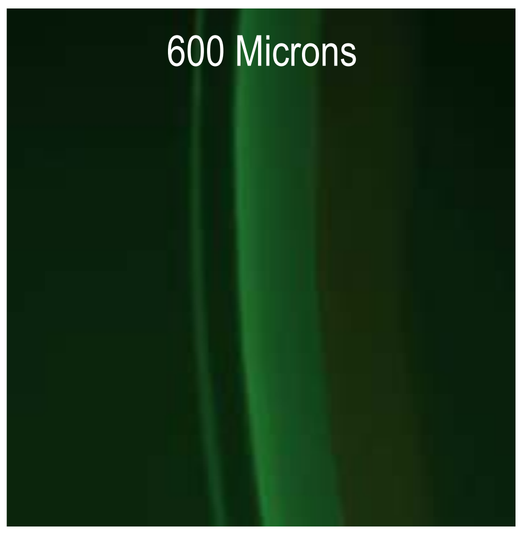
Central Vaulting



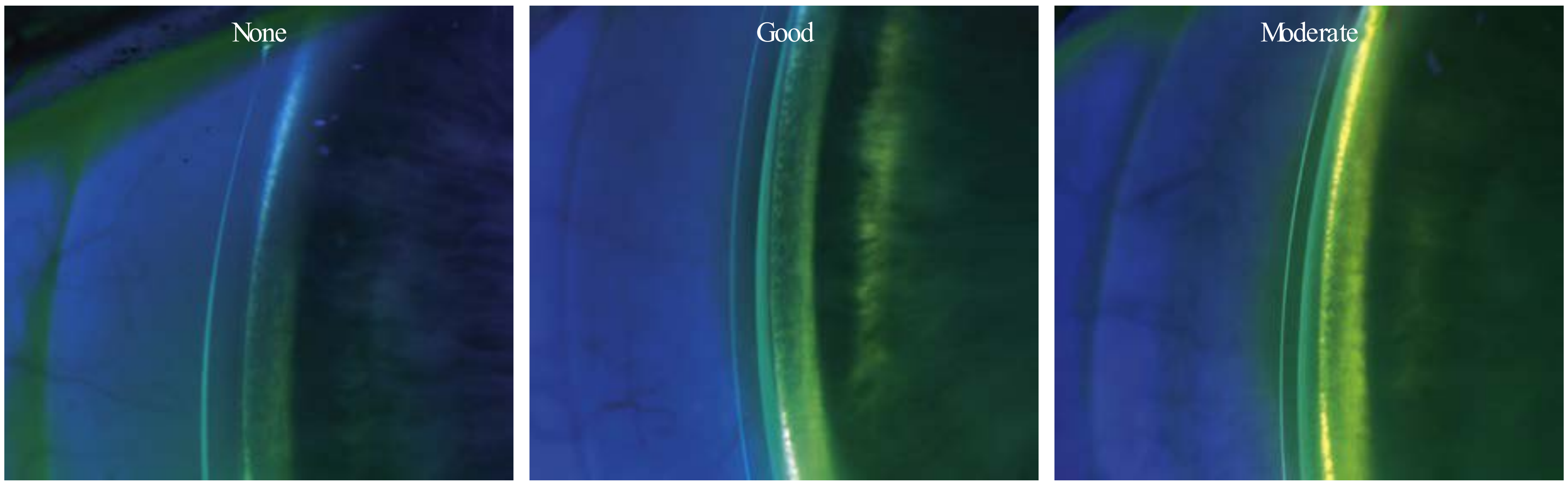

150 Microns


300 Microns

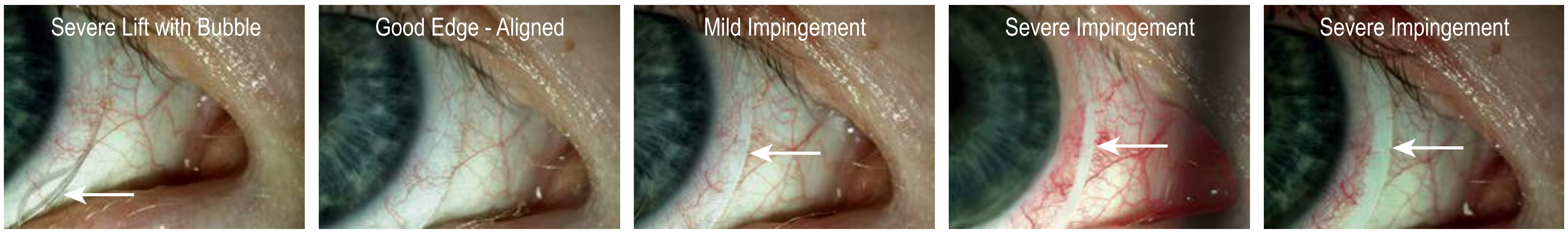

500 Microns


600 Microns

Limbal Vaulting


None
Good
Moderate

Edge Relationship


Severe Lift with Bubble
Good Edge - Aligned
Mild Impingement
Severe Impingement
Severe Impingement

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